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Guidance for the Reregistration of Pesticide Products Containing Picloram as the Active Ingredient

(U.S.) Environmental Protection Agency
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EPA

Guidance for the Reregistration of Pesticide Products Containing PICLORAM as the Active Ingredient

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

Picloram

AS THE ACTIVE INGREDIENT

OPP Number: 005101

CAS Number: 1918-02-1

September 30, 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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GLOSSARY OF TERMS AND ABBREVIATIONS

1985 Standard	Registration Standard issued March 29, 1985 for Picloram
ae	Acid equivalent
ai	Active ingredient
CAS	Chemical Abstracts Service (Number)
CSF	Confidential Statement of Formula
EC	Emulsifiable concentrate
EEC	Estimated Environmental Concentration
EP	End-use product
EPA	The Environmental Protection Agency, also "the Agency"
FIFRA	The Federal Insecticide, Fungicide, and Rodenticide Act
FWS	Fish and Wildlife Service
gal	Gallon
g/kg	Grams per kilogram
GSRI	Gulf South Research Institute
HCB	Hexachlorobenzene
HDT	Highest dose tested
IOE	Isooctyl ester of picloram
IPA	Isopropanolamine salt of picloram
K	Potassium salt of picloram
LDT	Lowest dose tested
LEL	Lowest-effect level
LOEL	Lowest-observable-effect level
MATC	Maximum allowable toxic concentration

mg/kg bwt/day	Milligrams per kilogram of body weight per day
mg/L	Milligrams per liter
MP	Manufacturing-Use product
MRID	Master Record Identification (Number) - EPA's system of tracking studies used in support of registration
NOEL	No-observed-effect level
NPDES	National Pollution Discharge Elimination System
NTP	National Toxicology Program
OPP	The Office of Pesticide Programs
PADI	Provisional acceptable daily intake
picloram	4-amino-3,5,6-trichloropicolinic acid
ppb	Parts per billion
ppm	Parts per million
Q_1^*	Potency
RAC	Raw agricultural commodity
R.F.D.	Considered to be the level unlikely to cause significant adverse health effects associated with a threshold mechanism of action in humans exposed to a toxicant for a lifetime.
SC/L	Soluble concentrate/liquid
Supplementary Data	Studies in this category maybe scientifically sound, thus the information may be useful. However, the studies were performed under conditions that deviated substantially from recommended protocols. These studies do not meet Guideline requirements and thus do not support registration of a product.
TEA	Triethylamine salt of picloram
TIPA	Triisopropanolamine salt of picloram
TGAI or Technical	Technical grade of the active ingredient

Technical Picloram	Technical grade of picloram or the acid form of picloram
TMRC	Theoretical Maximum Residue Contribution
TWA	Time-weighted averages
>	Greater than
<	Less than

I. INTRODUCTION

This document is a revised Registration Standard for the subject chemical. In its original Standard, issued on March 31, 1985, the Agency described the available data supporting the registration of the chemical. The Agency concluded that additional data were necessary to fully evaluate the pesticide. The Agency also set out label language which the Agency concluded at that time were needed to ensure that products containing the pesticide remained in compliance with FIFRA.

The Agency has since received and reviewed the additional data and has revised its scientific and regulatory conclusions in light of those data, other information on the chemical, and expanded data requirements promulgated in 1984, at 40 CFR Part 158, for registration and reregistration of pesticides under FIFRA.

This revised Registration, which supersedes the earlier Standard, is the Agency's updated scientific assessment of the pesticide, and the data needed to support its continued registration. The Agency has also reassessed the tolerances for the pesticide; that reassessment is included in this Registration Standard.

The Agency has also reviewed the current labeling for products containing the pesticide, and has specified label revisions which are necessary to remain in compliance with FIFRA.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

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[1] The scientific reviews and Compendium of Uses may be obtained from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22616. Tel: (703) 487-4650.

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submission of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICALS COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICALS

The following chemicals are covered by this Registration Standard:

Chemical Name: 4-amino-3,5,6-trichloropicolinic acid
Common Name: Picloram
CAS No.: 1918-02-1
OPP Chemical Code: 005101
Empirical Formula: $C_6H_3Cl_3N_2O_2$
Trade Name: Tordon
Chemical Characteristics: White powder which decomposes at 215 °C, bulk density of 19.7 pounds per cubic foot (lb/cu ft)

Chemical Name: Potassium salt of 4-amino-3,5,6-trichloropicolinic acid
Common Name: Picloram potassium (K) salt
CAS No.: 2545-60-0
OPP Chemical Code: 005104
Empirical Formula: $C_6H_2Cl_3KN_2O_2$

Chemical Name: Isooctyl ester of 4-amino-3,5,6-trichloropicolinic acid
Common Name: Picloram isooctyl ester (IOE)
OPP Shaughnessy No.: 005103
Empirical Formula: $C_{14}H_{19}Cl_3N_2O_2$

Chemical Name: Triisopropanolamine salt of 4-amino-3,5,6-trichloropicolinic acid
Common Name: Picloram TIPA salt
OPP Chemical Code: 005102
Empirical Formula: $C_{15}H_{24}Cl_3N_3O_5$

Chemical Name: Triethylamine salt of 4-amino-3,5,6-trichloropicolinic acid
Common Name: Picloram TEA salt
OPP Chemical Code: 005105
Empirical Formula: $C_{12}H_{18}Cl_3N_3O_2$

Chemical Name: Isopropanolamine salt of 4-amino-3,5,6-trichloropicolinic acid
Common Name: IPA salt of picloram

B. USE PROFILE

Type of Pesticide: Herbicide
Pests Controlled: Broadleaf weeds and woody plants

Registered Uses: Picloram, potassium salt: Terrestrial food crop use on small grains (spring barley, spring oats, spring and winter wheat), flax, pastures and rangeland grasses; Terrestrial nonfood use on noncrop agricultural areas and rights-of-way; Forestry use on forest lands site preparation.

Picloram, isooctyl ester: Terrestrial nonfood use on industrial sites (manufacturing sites, storage areas, and fencerows) and rights-of-way. Forestry use on forest trees site preparation.

Picloram, triisopropanolamine salt: Terrestrial food crop use on small grains (spring barley, spring and winter wheat), pastures, and rangeland. Terrestrial nonfood crop use on uncultivated agricultural areas, rights-of-way, and industrial sites (manufacturing and storage areas); Aquatic nonfood crop use on drainage ditchbanks; Forestry use on forest trees.

Picloram triethylamine salt: Terrestrial food crop use on pastures and rangeland.

Predominant Uses: Pasture and rangeland (57%), utility rights-of-way (29%), and forestry (13%).

Mode of Activity: Alters nucleic acid and protein synthesis

Formulations: (Represented Sec. 3 registrations of the potassium salt (K). Formulation Intermediate: 30% ae or 34.7% active ingredient (ae).
Pelleted: 2% ae or 2.3 ai, 5 ae or 5.8% ai, 10% ae or 11.6 ai, Soluble Concentrate, Liquid: 2 lb ae, or 24 ai, 24.4 ai, or 24.9% ai.

Basic Manufacturer: Dow Chemical USA
Year of Initial Registration: 1964
Methods of Application: By Ground: Broadcast or spot treatment as foliar or soil spray; as a basal spot treatment; broadcast as pelleted, spray, as tree injection, as frill treatment, as stump treatment, as basal bark treatment, as a wick application, and as low-volume dormant stem spray.
By Air: Broadcast or low volume dormant spray.

Rates of Application: (Section 3 registrations) Picloram, TIPA salt: 0.27 to 3.00 lb ae/A.
Picloram, IOE: 0.5 to 3.0 lb ae/A (mixtures or MAI).
Picloram, K salt: 1.0 to 8.50 lb ae/A.
Picloram, TEA salt: 0.25 to 1.0 lb ae/A (SLN's).

C. HISTORY

Picloram, 4-amino-3,5,6-trichloropicolinic acid, is a systemic herbicide registered for brush and broadleaf weed control. In 1978 the Agency classified picloram as a Restricted Use pesticide based on hazard to nontarget organisms (specifically nontarget plants both crop and noncrop). Considerable emphasis for restriction was based on recurring reports of phytotoxicity to such economically important crops as tomatoes, potatoes, tobacco, and succulent ornamentals caused by contaminated water supplies (1 part per billion [ppb]) range. This action was taken by the Agency through regulations proposed in the September 1, 1977 (42 FR 44170) and finalized in the February 9, 1978 (43 FR 5782) issues of the FEDERAL REGISTER.

On March 29, 1985, the Agency issued a Registration Standard for picloram. The Standard required the following: 1) precautionary label statements advising against the use of picloram in very permeable, i.e., well-drained soils such as karst limestone and loamy sands; 2) a groundwater monitoring study; 3) retention of Restricted Use classification; 4) additional wildlife testing on the technical; 5) a field monitoring study to determine concentrations of picloram in runoff water and sediment, leachate, groundwater, and in water and sediment of receiving aquifers to complete a hazard evaluation to wildlife; 6) development of analytical methods for metabolite residues in plant and animal samples; 7) storage stability data; 8) additional oncogenicity data; 9) limiting the level of hexachlorobenzene (HCB) in the technical to a maximum of 200 parts per million (ppm); 9) nontarget area phytotoxicity data on the technical; and 10) testing for nitrosamines and certification that the upper limit of nitrosamines occurring in the technical is not greater than 1 ppm.

The Standard concluded that reentry intervals were not required; that all forms (acid, esters, amines) were toxicologically similar, therefore, testing with the acid form would fulfill most data requirements for all forms; and that adequate residue data were not available to support established tolerances. Additional data required by the Standard included acute toxicology studies on the various forms of picloram, chronic feeding studies, oncogenicity data on the rat, a rabbit teratology study, avian oral and dietary studies, phytotoxicity studies, additional residue data, and additional environmental fate data.

All data submitted in response to the Standard have been reviewed and evaluated and previously submitted data have been reevaluated. The results of this review are discussed in the Agency Assessment section.

III. AGENCY ASSESSMENT

A. SUMMARY SCIENCE ASSESSMENT

Technical picloram is in Toxicity Category I with respect to acute inhalation and Categories III and IV with respect to other acute toxicities. Picloram has been classified as a Group D oncogen (not classifiable to human carcinogenicity). Available supplemental data indicate that picloram is not teratogenic to rats and causes no adverse reproductive effects. Repeat oncogenicity, teratology, and reproduction studies are being requested. Picloram appears not to be mutagenic based on available data.

Picloram is stable to hydrolysis, does not photodegrade under light, and is relatively stable in anaerobic loam soils and under anaerobic aquatic conditions. It also does not accumulate in fish. Picloram was intermediately to very mobile in soils ranging in texture from clay to loam. Picloram has been identified as a chemical with a potential to contaminate groundwater.

Picloram is practically nontoxic to avian species, slightly to moderately toxic to freshwater fish, and slightly toxic to freshwater invertebrates.

B. TOXICOLOGICAL CHARACTERISTICS

The Agency has registered several forms of picloram: the potassium (K) salt, the isooctyl ester (IOE), triisopropanolamine (TIPA) salt, and the triethylamine (TEA) salt. The isopropanolamine (IPA) salt of picloram and the acid form currently have no registered uses. In the 1985 Standard, the Agency considered the different forms of picloram to be toxicologically similar and required testing on the acid form to fulfill data requirements for all forms of picloram. Because there may be qualitative or quanitative difference in the behavior of the TEA, TIPA, IPA salts due to the amine moiety and the IOE due to the ester moiety and because either moiety may cause effects not seen with the acid or K salt a separate set of toxicology studies are required for the isoctyl esters and the amine salts. Therefore, for the purposes of this Standard, the acid and K salt forms are expected to act similarly and, lacking data to show otherwise, the organic ester and amines may be expected to have different qualitative and/or quantitative toxicological properties than the acid and the K salt and from each other.

Considering the common moiety, picloram, in each compound, the Agency is requiring complete toxicological testing of the acid and/or K salt. The Agency lacks basic toxicology (acute and subchronic feeding, mutagenicity, and teratology) data on the organic esters and amines of picloram. To evaluate applicator risk and to determine if the toxicity of these organic amines and esters differ significantly from the acid and each other, acute toxicology, subchronic feeding, teratology, and mutagenicity studies are required for the organic salts (TIPA, TEA, IPA) and extra forms of picloram. Refer to the discussion below and the data tables in Appendix I for specific requirements.

Acute Toxicology

An acute inhalation study places technical picloram acid in Toxicity Category I with an acute inhalation toxicity of 0.035 mg/L. Acute oral toxicity (females), acute dermal toxicity, and primary eye irritation studies place technical picloram acid in Toxicity Category III with an acute oral toxicity for females of 4012 mg/kg; an acute dermal toxicity > 2000 mg/kg, and moderate eye irritation. Primary dermal irritation and acute oral toxicity (males) studies place technical picloram in Toxicity Category IV with an acute oral toxicity to males > 5000 mg/kg and no erythema or edema observed in the primary dermal irritation study. Technical picloram was not a skin sensitizer in the dermal sensitization study.

An acute inhalation study places the K salt formulation intermediate in Toxicity Category II with an acute inhalation toxicity greater than 1.63 mg/L. Acute oral toxicity (females), acute dermal, and primary eye irritation studies place the K salt in Toxicity Category III with an acute oral toxicity to females of 3536 mg/kg; an acute dermal toxicity > 2000 mg/kg, and moderate eye irritation. Primary dermal irritation and acute oral toxicity (males) studies place the K salt in Toxicity Category IV with an acute oral toxicity to males > 5000 mg/kg and no erythema or edema observed in the primary dermal irritation study. A dermal sensitization study showed that the K salt form of picloram was a skin sensitizer.

An acute inhalation study places the IOE form of picloram in Toxicity Category II with an acute inhalation toxicity > 0.35 mg/L. Acute oral toxicity, acute dermal toxicity, eye irritation, and dermal irritation studies place the IOE form of picloram in Toxicity Category III with mild skin irritation, moderate eye irritation, an acute oral toxicity > 3500 mg/kg (males and females), and an acute dermal toxicity > 2000 mg/kg. A dermal sensitization study showed that the IOE form of picloram was a skin sensitizer.

There are no acute toxicology data available for the TIPA, TEA, or IPA salts of picloram. These data are required.

Subchronic Toxicity

An acceptable 13-week subchronic feeding of technical picloram acid study in rats fed dosages of 0, 15, 50, 150, 300, or 500 mg/kg has been submitted. A dose-dependent increase in absolute and relative liver weights was seen at 150 mg/kg. Effects were minimal and showed a NOEL of 50 mg/kg.

An acceptable 6-month feeding study with dogs fed dosages of 0, 7, 35, or 175 mg/kg/day of technical picloram acid has been submitted. A decrease in food consumption and increases in liver weights at the highest dose and increased liver weights were noted in males at 35 mg/kg (lowest effect level [LEL]) resulting in a NOEL of 7 mg/kg.

No subchronic feeding studies are available for the TIPA, TEA, IOE, or IPA forms of picloram. Subchronic feeding studies in a rodent and a nonrodent are required for each form of picloram.

No data are available on the 21-day subchronic dermal toxicity of picloram. This was not a data requirement in the 1985 Standard because the toxicology review was completed before the 1984 Guidelines were finalized which require a 21-day dermal study when dermal exposure is estimated to be of limited frequency and duration. Therefore, because existing use patterns may result in limited exposures of short duration, a 21-day dermal study is required for picloram acid (or K salt), the TIPA, IPA, TEA, and IOE forms of picloram.

No data are available on the 90-day subchronic dermal toxicity of picloram. A study is not required because existing use patterns do not involve purposeful or prolonged dermal exposure (not used on clothing or in swimming pools).

No data are available on the 90-day subchronic inhalation toxicity of picloram. A study is not required because the present use patterns do not result in repeated inhalation exposure (not used on tobacco).

Neurotoxicity

There are no data available for acute delayed or subchronic delayed neurotoxicity for either picloram or its salts, esters, and amines. Acute delayed neurotoxicity studies are not required because picloram and its salts, esters, or amines are not organophosphates. Subchronic delayed neurotoxicity testing is not required because acute delayed neurotoxicity testing is not required.

Chronic Toxicity

A acceptable 2-year chronic feeding study with rats fed dosages of 20, 60, or 200 mg/kg/day of technical picloram has been submitted. A significant dose-related histologically determined increase in size and altered tinctorial properties of centrilobular hepatocytes occurred in both males and females at 60 and 200 mg/kg/day. The NOEL for this study is 20 mg/kg day. This study is acceptable and satisfies the requirement of a chronic feeding study in a rodent.

A chronic feeding study for nonrodents was required by the 1985 Standard. This study was not submitted in time to be included in standard.

Oncogenicity

Available oncogenicity data for picloram include rat and mouse studies performed by the National Toxicology Program (NTP) and a rat study performed by Dow Chemical Company. These studies are discussed below.

In a study performed by the NTP by Gulf South Research Institute (GSRI), Osborne-Mendel rats were fed picloram (technical grade 90% pure with 130 ppm HCB) at dosages corresponding to time weighted average (TWA) dosages of 372 mg/kg/day (7437 ppm) and 747 mg/kg/day (14,875 ppm) for 80 weeks. At the highest dose, 747 mg/kg/day, an oncogenic effect (neoplastic nodules) was seen in females. This study was classified as supplementary data for the following reasons: the matched control group was of insufficient size, a shorter than 2-year (lifetime) exposure limit was used, and insufficient data and information were provided by available chronic and subchronic studies to determine if a maximum tolerated dose (MTD) was attained at 747 mg/kg/day.

In a second NTP study, $B_6C_3F_1$ mice were fed picloram (technical grade 90% pure with 130 ppm HCB) at dosages of 357 and 714 mg/kg/day for 79 weeks and allowed to recover 10 weeks prior to sacrifice. Picloram did not show an oncogenic response up to 714 mg/kg/day for 79 weeks. This study initally considered acceptable is classified as supplementary data because available information do not assure that an MTD was attained in this study.

In a study submitted by Dow in response to the 1985 Standard, Fisher 344 rats were fed doses of 0, 20, 60, and 200 mg/kg/day picloram (technical grade 93% pure with 197 ppm of HCB) for 2 years. No dose-related oncogenic effects were observed in either male or female rats. This study was initially classified as an acceptable study. However, upon rereview, it was determined inadequate for determining the potential oncogenicity of picloram to rats (MTD not determined, testing must be conducted on technical picloram uncontaminated by HCB).

In its evaluation, the Agency notes that the above studies have problems related to experimental design and good laboratory practices (GLP) issues, dosing concerns (some of the studies appeared to be conducted using inadequately low doses), and the presence of the contaminant HCB in the technical grade picloram. HCB has been known to produce liver tumors in some strains of rodents. As a result, EPA classified picloram as a Group D oncogen (not classifiable as to human carcinogenicity) based on the EPA Guidelines and the weight of the following two biological evidence considerations: First, although an oncogenic effect considered to be "equivocal evidence" of carcinogenicity by the NTP was seen at the highest dose level tested in one sex of one species (liver adenomas/carcinomas combined in female Osborne-Mendel rats) the presence of relatively high levels of HCB in technical grade picloram was suspected to be responsible for the occurrence of the liver tumors. EPA was informed that these levels are greater than those found in commercially marketed picloram. The study was further confounded because of inadequate dosage levels, duration of exposure and control group, and possible GLP deficiencies. Second, bioassays in $B_6C_3F_1$ mice and in a second strain of rat (Fischer 344) were negative for oncogenicity, but were considered inadequate for determining the potential oncogenicity of picloram because of similar confounding factors.

The Agency believes that the chronic rodent oncogenicity studies of picloram contained major qualitative/quantitative limitations and could not be accurately interpreted as showing either the presence or absence of an oncogenic effect. The absence of a positive oncogenicity correlation from two structurally similar pesticides, and generally negative findings from short-term mutagenicity studies, were also noted.

Because of the deficiencies in the picloram oncogenicity studies, long-term studies in Osborne-Mendel rats and $B_6C_3F_1$ mice of both sexes, conducted according to EPA Guidelines and the EPA Position Paper on the MTD using commercially available technical grade picloram uncontaminated with potentially tumorigenic levels of HCB, are required.

No oncogenicity data are available for the ester or amines of picloram and studies are not required at this time pending submission and review of acute toxicology studies, subchronic toxicology, and teratology studies required by this document (refer to data tables in Appendix I for detailed requirements for the ester and amine forms of picloram).

Teratogenicity

Available teratology studies for picloram include a rabbit teratology, submitted in response to the 1985 standard and a rat teratology study. These studies are discussed below.

A teratology study in rabbits using the K salt of picloram, dosed by gavage at 0, 40, 200, or 400 mg/kg, showed that the maternal LEL was 200 mg/kg and the maternal NOEL was 40 mg/kg based on reduced body weight gain during gestation. Fetal abnormalites (severe rib fixture or missing ribs, hypoplastic tail, omphalocele) were noted at 200 and 400 mg/kg. Historical control data were not presented in this study and are needed to evaluate the observed fetal abnormalities. Therefore, to fulfill this requirement, the historical control data or a new study with rabbits must be submitted.

In the 1985 Standard, the Agency concluded that a study in which rats were dosed with 500, 750, or 1000 mg/kg was adequate to show that picloram did not produce a teratogenic effect at up to 1000 mg/kg/day. The review for that standard was completed before finalization of 1984 Guidelines (October 24, 1984, 49 FR 42856). Upon reevaluation in accordance with the revised guidelines, some fetotoxicity (increased incidence of delayed ossification of 5th sternebrae) was noted. No NOEL for fetotoxicity was found. Maternal toxicity was also noted at 750 and 1000 mg/kg as hyperactivity and mild diarrhea. A repeat teratology study in the rat is required.

No teratology studies are available for the esters or amines of picloram. Therefore, teratology studies in rat and rabbits are required for all the esters and amines of picloram.

Reproduction

A multigeneration reproduction study in rats fed dosages of 0, 1.5, 50, and 150 mg/kg/day was previously submitted and determined acceptable in the 1985 Standard. No reproductive effects were observed. The review of this study was completed before finalization of the 1984 Guidelines (October 24, 1984 49 FR 42856). Upon reevaluation of this study under the 1984 Guidelines, this study is now classified as supplementary data because too few test animals were used and no toxicity was observed at the highest dose tested. Therefore, a 2-generation reproduction study with rats is required for picloram.

No reproduction studies are available for the esters and amines of picloram and none are required at this time pending submission and review of acute toxicology, subchronic toxicology, and teratology studies requested by this document (refer to data tables in Appendix I for detailed requirements of the ester and amine forms of picloram).

Mutagenicity

An Ames test was submitted in response to the 1985 standard testing picloram with *Salmonella typhimurium* with and without activation. Based on qualitative statements, picloram did not produce mutagenic effects. This study is classified as supplementary data since only qualitative statements were submitted. Therefore, a new study is required or the data and raw report materials must be submitted for the study on hand.

A cytogenetic (bone marrow cells) study in rats exposed to single doses up to 2000 mg/kg picloram did not show evidence of chromosomal changes. This study satisfies the requirement for chromosomal aberrations for technical picloram.

No data are available on the evaluation of the direct DNA-damaging potential of picloram. These data are required for technical picloram (or its K salt), its amines, and esters.

Data are required to satisfy requirements for gene mutation and chromosomal aberrations for all esters and amines of picloram.

Metabolism

A metabolism study using only male rats is available for picloram. Three male rats were dosed orally with 1.634, 9.6, or 184 mg/kg. The three rats gave mean excretion values of 82.28 ± 2.78 percent of the dose in urine, 15.52 ± 2.04 percent of the dose in feces, < 0.0006 percent of the dose in CO_2, and 0.57 ± 0.18 percent in cage washings; for a total of 98.37 ± 1.21 percent recovered after 72 hours. This study alone does not satisfy the requirement since testing was not on both sexes as required by the 1984 Guidelines. An additional study in female rats is required for technical picloram (or the K salt). Data are required for all esters and amines of picloram in both male and female rats.

C. MANUFACTURING IMPURITIES

1. Hexachlorobenzene

Technical picloram contains the impurity HCB, at a maximum of 200 ppm. Because HCB is classified as a Probable Carcinogen (Group B2), a dietary risk assessment was included in the 1985 Standard. This assessment estimated the risk in the fat and milk of cattle fed picloram treated grass to be 4.6×10^{-8} for a 70 kg adult and 1.4×10^{-7} for a 10 kg child This assessment has been updated and is discussed below.

Hazard Profile of HCB in Picloram

Oncogenic Effects

In January 1985, the Agency published a Health Assessment Document for Chlorinated Benzenes (MRID No. 405430-01).** The conclusions from that document were used to perform the following risk assessment. A brief summary of the qualitative and quantitative oncogenic assessment from that document is presented below. For an in-depth discussion, refer to Section 12 of the document.

Assuming that HCB is oncogenic in humans, the Agency estimated an upper-bound incremental unit cancer risk. Four animal studies were adequate for use in estimating the Q_1* (i.e., potency).

Fourteen data sets which show significant increases of tumor incidences were used to calculate the carcinogenic potency of HCB. These include hepatomas and hemangioendothelioma of the liver in both sexes and thyroid adenomas in male Syrian golden hamsters (Cabral et al., 1977), hepatomas in both sexes in Swiss mice (Cabral et al., 1979), renal cell adenoma, hepatocellular carcinoma, and hepatoma in both sexes of Sprague-Dawley rats (Lambrecht 1983) and adrenal pheochromocytoma in female Sprague-Dawley rats (Arnold et al., 1985). The Q_1* obtained from the hepatocellular carcinomas in the female Sprague-Dawley rats was used to calculate the cancer unit risk and is used to calculate the risk as a result of exposure to HCB from the uses of pesticide products containing picloram. The estimate of greatest potency was determined to be:

$$Q_1^* = 1.7 \text{ (mg/kg/day)}^{-1}$$

** 40543001 U.S. Environmental Protection Agency (1984) Health Effects Assessment for Hexachlorobenzene: EPA/ 54C/186-C17). Prepared by Syracuse Research Corp., under EPA Contract 68-03-3112, for the Office of Solid Waste and Emergency Response, Washington, D.C. 43 pages.

Other Toxic Effects

A 4-generation reproductive toxicity study of HCB in rats produced a NOEL of 20 ppm (1 mg/kg/day). The primary toxic effect observed was toxicity to the nursing pups. The effect was lethal at higher doses. No teratogenic effects were seen. The NOEL for maternal toxicity was 80 ppm (4 mg/kg/day).

Risks from Dietary Exposure

Potential dietary exposures to the impurity HCB may occur from the use of pesticides containing picloram on small grains and secondary residues on animal commodities resulting from use on pastures and rangeland. Tolerances for picloram do not include allowable residues for HCB. Because there are no actual crop residue data for HCB, estimates of potential dietary exposures to it from picloram use were calculated using picloram tolerance levels. The Agency is requiring analyses for residues of HCB in or on agricultural commodities derived from crops treated with pesticides containing picloram.

In estimating dietary exposures, it was assumed that residues of HCB would be present at 0.02 percent of picloram tolerance levels, the maximum legal level of HCB contamination in technical picloram and that 100 percent of the crops would be treated with picloram.

Based on available information, oncogenic risk was estimated for the overall U.S. population in accordance with current Agency policy. This value was calculated by the relationship:

$$\text{Risk} = \text{Exposure} \times Q_1^*$$

$$\text{Risk} = 3.67 \times 10^{-7}\ \text{mg/kg/day} \times 1.7\ (\text{mg/kg/day})^{-1}$$

$$\text{Risk} = 6 \times 10^{-7}$$

Risks from Nondietary Exposure

Potential nondietary exposure to HCB is to workers, mixer-loaders, and applicators from uses of picloram on wheat, forests, rights-of ways, and pasture/rangeland. To estimate worker exposure, the following assumptions were made: technical picloram is assumed to contain 200 ppm of HCB; an average worker weighs 70 kg; a ground applicator treats 100 acres of wheat per day at a rate of 0.02 lb ae/A with an actual treatment time of 6.0 hours; private applicators are assumed to work 3 days/year and commercial applicators 15 days/year; an aerial applicator treats 600 acres of pasture/rangeland per day with picloram at a typical rate of 0.5 lb ae/A and a maximum rate of 4.0 lb/A (actual treatment time is 7.5 hours/day); workers are assumed to spend 10 days/year treating pasture/rangeland; for aerial application, separate individuals perform mixer/loader, flagger, and applicator (pilot) tasks.

The picloram label does not require the use of protective clothing or a closed loading system. Dermal exposures for mixer/loaders are calculated from surrogate data available.

Data for the assessment for exposure to HCB from forestry uses of picloram were taken directly from U.S. Department of Agriculture Forest Service data on phenoxy herbicides (2,4-D and 2,4,5-T). Estimates of potential exposure to picloram are based on aerial and ground application. The maximum aerial application rate for picloram is 1.9 lb ae/A, while the compound is applied from the ground at rates as high as 10 lb ae/A. Risk was calculated by calculating a lifetime average daily dose (LADD) which then multiplied by the Q_1^*.

Exposure data for the use on rights-of way are not available; however, exposure rates for aerial application are expected to be lower than those estimated for pasture/rangeland use, and exposure rates for ground application are expected to be lower than those estimated for forest use.

The Agency considers the dietary risk and nondietary risk from HCB to be acceptable provided that HCB levels in the technical product do not exceed the certified limits of 200 ppm. Refer to Chart entitled "HCB - Risk Characteristics" for exposure and risk calculations.

HCB - Risk Characteristics

	Exposure		Risk
	1. mg/kg/yr	2. mg/kg/day (lifetime) $1. \times \frac{1}{365} \times \frac{35}{70}$	2. x Q* (mg/kg/day)$^{-1}$ (2. x 1.7)
Ground Boom (wheat)			
Private			
Mixing/loading	1.6×10^{-5}	2.2×10^{-8}	4×10^{-8}
Applying	4.8×10^{-6}	6.0×10^{-9}	1×10^{-8}
Combined	2.0×10^{-5}	2.8×10^{-8}	5×10^{-8}
Commercial			
Mixing/loading	8.0×10^{-5}	1.1×10^{-7}	2×10^{-7}
Applying	2.4×10^{-5}	3.3×10^{-8}	6×10^{-8}
Combined	1.0×10^{-4}	1.4×10^{-7}	2×10^{-7}
Aerial (range/pasture) [0.5 lbs ae/acre)			
Mixing/loading	8.0×10^{-3}	1.1×10^{-5}	2×10^{-5}
Applying	6.4×10^{-5}	8.0×10^{-9}	2×10^{-8}
Flagger	3.6×10^{-5}	5.0×10^{-8}	8×10^{-8}
[40 lbs ae/acre]			
Mixing/loading	6.4×10^{-2}	9.0×10^{-5}	2×10^{-4}
Applying	5.2×10^{-5}	7.2×10^{-8}	1×10^{-7}
Flagger	2.9×10^{-4}	4.1×10^{-7}	7×10^{-7}
Forestry			
Mixing/loading	2.0×10^{-2}	2.8×10^{-5}	5×10^{-5}
Obsever	1.5×10^{-3}	2.1×10^{-6}	4×10^{-6}
Backpack sprayer	8.0×10^{-3}	1.1×10^{-5}	2×10^{-5}

2. Nitrosoamines

The 1985 standard established an upper limit of no greater than 1 ppm for the presence of nitrosoamines in technical picloram. Nitrosoamines are a potential contaminant of the tertiary amines (TEA) and alkanolamine (TIPA) forms of picloram. Testing is required for TEA and TIPA to show that a level of 1 ppm nitrosoamine contamination is not exceeded. Refer to 45 FR 42854 for discussion. Testing requirements are discussed in the data tables in Appendix I.

D. PHYSIOLOGICAL AND BIOCHEMICAL BEHAVIOR CHARACTERISTICS

Picloram translocates from both the roots and leaves of plants and accumulates in the new growth. Picloram is both foliar-absorbed and root absorbed. When picloram is applied to foliage it moves in the phloem and xylem tissues and when applied to the soil picloram moves rapidly in the xylem.

The mode of action of picloram involves altering of nucleic acid and protein synthesis by affecting a variety of enzymes.

Available plant metabolism data indicate that picloram degrades to CO_2, oxalic acid, and the metabolites 4-amino-2,3,5-trichloropyridine and 4-amino-3,5-dichloro-6-hydroxypicolinic acid.

Available metabolism data in poultry indicate that 99.9 percent of the recovered radioactivity is found in the excreta and that 98 to 99 percent of the ^{14}C residues are characterized as picloram. Radioactivity in the kidney was also identified as picloram (91 to 94%) and 82 to 88 percent of the radioactivity in the liver was characterized as picloram. Available metabolism data in lactating goats indicate that 90 to 96 percent of the administered ^{14}C activity recovered in the urine and feces was identical to the [^{14}C]picloram used in dosing the animals. These data indicate that picloram is not metabolized by animals.

E. ENVIRONMENTAL CHARACTERISTICS

In an acceptable hydrolysis study submitted in response to the 1985 Standard, the ring-labeled isooctyl ester of picloram degraded with half-lives of > 28 days (calculated 61.5 days) in sterile aqueous buffered pH 5 solutions, approximately 28 days (calculated 38.7 days) in pH 7 solutions, and 3.5 to 21.5 hours (calculated 18.4 hours) in pH 9 solutions incubated in the dark at 25 °C.

In an acceptable hydrolysis study reviewed under the 1985 Standard, labeled picloram in dilute phosphate buffers (pHs 5, 7, and 9) showed that greater than 90 percent of the picloram remained after 70 days. The estimated half-life was greater than 1.8 years at 45 °C. This study was reevaluated for this Standard and determined acceptable to fulfill Guideline requirements.

In an acceptable aerobic metabolism study submitted in response to the 1985 Standard, the ring-labeled isooctyl ester degraded with half-lives of < 2 days in clay loam soil, 2 to 4 days in silt loam soil, and 4 to 7 days in sandy loam soil under aerobic conditions. Picloram and CO_2 were the only degradates found. Picloram was relatively stable in anaerobic loam soil incubated in the dark and under anaerobic aquatic soil conditions.

In an acceptable aerobic metabolism study reviewed under the 1985 Standard, ring-labeled picloram degraded with half-lives of 100 to 200 days in Holdridge loam and uncharacterized soils; 200 to 300 days in silt loam soil, and > 300 days in loamy sand, commerce loam, clay, and sandy loam soils under aerobic conditions. The major degradate was CO_2. This study was reevaluated for this Standard and determined acceptable to fulfill Guideline requirements.

In an acceptable fish accumulation study reviewed under the 1985 Standard, picloram residues did not accumulate in bluegill sunfish. This study was reevaluated for this Standard and determined acceptable to fulfill Guideline requirements.

Photodegradation studies in water considered partially acceptable in the 1985 standard upon re-evaluation were considered unacceptable by the 1984 Guidelines. In a photodegradation in water study submitted in response to the 1985 Standard picloram IOE degraded with a half-life of 1 hour (calculated 1.1 hours) in sterile aqueous buffered pH 5 solutions that were irradiated with phosphor-coated mercury lamps. This study does not fulfill guideline requirements because the artifical light source was not similar to sunlight.

In a soil photodegradation study submitted in response to the 1985 Standard, picloram did not degrade during 384 hours of irradiation with a mercury arc lamp. Picloram comprised 90 percent of the applied radioactivity in the irradiated soil and 96.7 percent of applied radioactivity in the dark control 384 hours posttreatment. This study does not fulfill guideline requirements because the artifical light used was not similar to sunlight.

In a leaching and absorption study considered acceptable in the 1985 Standard, picloram was intermediately mobile to very mobile in soils ranging in texture from clay to loam. Absorption of picloram increased with increasing soil matter and decreasing soil solution pH. Addition of inorganic salts to the soil did not affect adsorption of picloram. In another leaching and adsorption/desorption study considered in the 1985 Standard, 27 percent of the applied carboxyl-labeled [^{14}C]picloram was adsorbed by loam soil during 14 days of equilibrium at 25 °C with a buffered pH 7 aqueous solutions (soil:solution ratio 1:4) containing 0.25 ppm of picloram. Seventy-one percent of the applied [^{14}C]picloram was absorbed by loam soil after 23 days of shaking at 25 °C in buffered pH 7 aqueous solutions (soil: solution ratio 1:4) containing 0.25 ppm of picloram. The review of these studies was completed before finalization of the 1984 Guidelines (49 FR 42856). Under these guidelines these studies are classified as supplementary data.

A field dissipation study submitted in response to the 1985 Standard evaluating dissipation and leaching of picloram provided the information that follows.

Picloram dissipated with an estimated half-life of 34 days in a field plot of sand and sandy loam soil. In the 0- to 6-inch soil depth, picloram declined from a maximum of 0.2 ppm 5 days posttreatment to $\leq$ 0.01 ppm by day 174. In the 6- to 12-inch depth, picloram reached a maximum of 0.03 ppm by day 21 and declined to < 0.005 ppm by day 100. In the 12- to 24-inch depth, picloram was < 0.005 ppm at all sampling intervals. In the 24- to 36- and 36- to 48-inch depths, picloram was a maximum of 0.02 ppm at day 14 (first time the 24 to 36-inch depth was sampled) and declined to $\leq$ 0.005 ppm by day 21. This study does not fulfill guideline requirements because no freezer storage stability data were provided and the soil may not have been sampled to an adequate depth to define the extent of leaching.

No picloram was detected in any of the water samples taken from two wells inside and downhill from the field plot (slope 0-4%, distance to water table 22.3 feet).

In a forestry dissipation study submitted in response to the 1985 Standard picloram degraded with a half-life of < 28 days in the upper 7 cm of forest soils (uncharacterized) in North Carolina that had been treated with the K salt of picloram (Tordon 10K, 10% ae P/T formulation) at 5 kg ai/ha. Picloram declined from 11.58 ppm at 16 days posttreatment (first sampling: 1 day following the first rainfall) to 2.21 ppm at 28 days and 0.06 ppm at 215 days. In samples taken from deeper soil, initial concentrations of picloram were 3.8 ppm in the 15 cm depth (16 days), 1.63 ppm in the 30 cm depth (16 days), 0.98 ppm in the 22 cm depth (28 days) 0.45 ppm in the 60 cm depth (70 days), and 0.13 ppm in the 120 cm depths (70 days). At 215 days posttreatment, picloram was ≤ 0.04 ppm at the 15 through 120 cm depths. In soil solutions obtained using lysimeters, picloram was ≤ 174 ppb at the 30 cm depth (maximum 3 months posttreatment), ≤ 179 ppb at the 60 cm depth (maximum 5 months), and ≤ 2 ppb at the 120 cm depth. Picloram was detected in water from downslope springs 18 times during 10 months of sampling and never at > 1.0 ppb; picloram was first detected at 7 months posttreatment. Picloram was ≤ 3 ppb in the upper stream sampling site (maximum 1 month posttreat ment); picloram was detected twice at the lower stream site, once at 2 ppb and once at 8 ppb (2 months posttreatment). This study do not fulfill guidelines because pretreatment and/or immediate posttreatment data were not reported for soil and water; the soils were incompletely characterized; the soils were not sampled deep enough to determine the extent of the leaching; and no foliage, leaf litter, standing water, or sediment samples were taken.

The 1985 standard required aerobic aquatic testing for aquatic nonfood uses. The registrant requested a waiver based on the position that there were no registered aquatic nonfood uses. The use on outer ditch banks is an aquatic use and must be supported by the required data.

Picloram (free acid) is formulated into two chemical forms: three salt forms (triisopropanolamine, potassium, and triethylamine) and one ester form (isooctyl). For the purpose of conducting environmental studies, a free acid/salt form and isooctyl ester form of picloram are the required test substances for most of the studies. The exception to this is the required terrestrial field dissipation studies which require all three registered formulations of picloram. Refer to data tables in Appendix I for testing requirements.

F. GROUNDWATER CONTAMINATION

Picloram has been previously identified as a pesticide with a propensity to leach into groundwater. Picloram was classified as a "Restricted Use" pesticide by regulations proposed in 1977 (42 FR 44171) and finalized in 1978 (43 FR 5792) partially on recurring reports of phytotoxicity to such economically important crops as tomatoes, potatoes, tobacco, legumes, and succulent ornamentals caused by contaminated water supplies (1 ppb range) from runoff and leaching. The 1985 Standard retained the "Restricted Use" classification and required that a groundwater advisory statement be included on the label. Additional dissipation data and a retrospective groundwater monitoring study were required by the 1985 Standard.

Picloram has been reported as detected in seven states, Kansas, Missouri, Minnesota, North Dakota, New York, South Dakota, and Wisconsin. All of these detections have been attributed to normal field use of picloram.

The data discussed above, in the Environmental Section, indicate that picloram is persistent and mobile and has a high potential to reach groundwater. This is corroborated by reports from several States of detection of picloram in groundwater.

Because available data indicate that picloram has a high potential to contaminate groundwater and available pesticide incident reports indicate loss of economically important crop from irrigation by water contaminanted with low levels of picloram the Agency will retain the "Restricted Use" due to groundwater contamination.

Since completion of the 1985 Standard, the Agency has approved a request to convert the required retrospective monitoring study to a prospective groundwater monitoring study. This study is due in July 1989. Further data may be required if it is determined that a more widespread characterization of the groundwater contamination hazard is needed.

The Agency has also approved a request to revise the groundwater statement required by the 1985 Standard. The Agency will retain the approved groundwater advisory statement.

G. EXPOSURE AND REENTRY

Based on available acute toxicology data, the major routes of concern appear to be through inhalation exposure. Although technical picloram (free acid) is placed in Toxicity Category I because of inhalation, there is little chance of exposure to mixer/loaders or applicators because there are currently no products registered containing the free acid (technical) form of picloram.

Reentry data or intervals are not required for picloram because cultural practices for existing uses (pasture/rangeland, rights-of-way, forestry, and small grains) indicate little likelihood that field workers would be exposed to acutely toxic levels of picloram following agricultural applications.

H. ECOLOGICAL CHARACTERISTICS

Terrestrial Organisms

Based on acute oral toxicities > 2250 mg/kg/day (technical) and > 2510 mg/kg/day (K salt) to mallard ducks, picloram technical and K salt are practically nontoxic to avian species on an acute basis. Available data indicate that 8-day dietary toxicity of picloram technical is > 5000 ppm for mallard ducks and bobwhite quail, that the 8-day dietary toxicity for the picloram K salt is > 5620 ppm for bobwhite quail, and that the 8-day dietary toxicity for the IOE of picloram is > 5620 ppm for bobwhite quail. Based on these data, technical picloram, its K salt, and its IOE form are practically nontoxic to avian species on a chronic basis. The requirements for acute oral toxicity and dietary toxicity tests with avian species have been satisfied. Additional testing will not be required on picloram derivatives (potassium salt, isooctyl ester) because of similarity in toxicity values that were noted in available data.

Technical picloram is relatively nontoxic to honey bees. Available data indicate that the 48-hour contact toxicity to honey bees is 14.5 micrograms per bee. This requirement is fulfilled for technical picloram. Honey bee acute testing is required for all salts, esters, and amine forms of picloram.

Aquatic Organisms

Based on acute toxicities ranging from 4.3 to 19.3 ppm (trout) and 14.5 to 23.0 ppm (bluegill), technical picloram appears to be moderately to slightly toxic to coldwater fish and slightly toxic to warmwater fish. Based on acute toxicities of 13 ppm (rainbow trout), 14 ppm (catfish), and 24 ppm (bluegill) the K salt of picloram is slightly toxic to freshwater fish. The isooctyl ester of picloram is moderately toxic to fish with acute toxicities of 1.4 ppm (catfish), 4.0 ppm (rainbow trout), and 6.3 ppm (catfish). The requirements for acute fish toxicity testing have been fulfilled. Additional acute testing of picloram salts, esters, and amines are not required because of the similarity in toxic values noted in available data.

In a fish-embryo larvae test, picloram caused a reduction in larval survival at 2.02 ppm and a reduction in growth at 0.88 ppm. In a chronic study designed to simulate picloram (acid) runoff following successive rainfalls, data suggest that picloram may affect survival and growth of cutthroat trout alevins at a concentration of 0.29 ppm. The requirement for fish early life stage testing with picloram technical acid has been fulfilled.

Picloram appears to be slightly toxic to aquatic invertebrates (daphnids, gammarus, *Pteronarcella*, and *Pteronarcys*) with an acute range of 10 to 68.3 ppm. Chronic testing showed that picloram toxicity caused a reduction in daphnid brood size and the number of young at 18.1 ppm. This chronic level suggests that picloram is only slightly toxic to daphnids. The requirements for acute and chronic invertebrate testing have been fulfilled. Additional acute or chronic invertebrate testing are not required for the salts, esters, or amines of picloram because of the similarity in toxic values noted in available data.

A field monitoring study to determine concentrations of picloram in runoff water and sediment, leachate, groundwater, and in water and sediment of receiving aquifers was required by the 1985 Standard. Subsequently the Agency determined that this study would not be required.

Picloram is water soluble and there is a potential for aquatic exposure through runoff and leaching. In assessing the hazard to aquatic life, the Agency calculated the Estimated Environmental Concentrations (EEC) of picloram in the water. Using the standard Agency pond model of 10 acres of runoff feeding into a 1-acre pond 6 ft deep, maximum residues were calculated for the major applications of picloram (rangeland, rights-of-way, and forestry). The expected picloram residues for pastures/rangeland and rights-of-way are below the acute toxicity values for fish and invertebrates by one to two orders of magnitude (acute toxicities of 0.5 to 0.68 ppm and EEC of 0.02 to 0.12 ppm). Based on this information, picloram does not appear to be an acute hazard to fish. However, picloram ground application for forestry could produce residues of 0.26 ppm which are comparable to chronic toxicity effects to the cutthroat trout larvae (growth and survival effected at about 0.29 ppm). Because the expected runoff from picloram (0.26 ppm) is less than the effect level (0.29 ppm) to larvae and the model used is considered a "worst case" only minimal concern exists at this time. This affect will be re-evaluated once required environmental fate data are submitted.

Plant Protection

In the 1985 Standard, Tier I nontarget area phytotoxicity data were required. Most of the studies submitted in response to the 1985 Standard were not acceptable to fulfill the requirements. However, available data indicate that picloram with a phytotoxicity of 36.41 mg/L (cells/mL) is not expected to exert a detrimental effect on the algae Selenastrum capricornutum when applied at current maximum rates. Additional Tier I testing will not be required since Tier II testing is required.

Because picloram is a herbicide, Tier II phytotoxicity testing (see Data Tables) is required to establish toxicity to nontarget plants. These tests are required for the technical picloram, its salts, amines, and esters because no comparative studies are available.

Phytotoxicity

In 1978, the Agency classified picloram as a Restricted Use pesticide through regulations proposed in the September 1, 1977 (42 FR 44170) and finalized in the February 9, 1978 (43 FR 5782) issues of the FEDERAL REGISTER. The criteria influencing the restriction was hazard to nontarget organisms (specifically nontarget plants both crop and noncrop) and recurring reports of phytotoxicity to such economically important crops as tomatoes, potatoes, tobacco, legumes, and succulent ornamentals caused by contaminated water supplies (1 ppb range) from runoff and leaching.

In the 1985 Standard, the Agency retained the "Restricted Use" classification based on phytotoxicity.

Because of recurring reports of loss of ecomonically important crops due to phytotoxicity from drift or contamination of irrigation water the Agency will retain the "Restricted Use" classification. The groundwater advisory will aid in reduction of risk to nontarget plants by advising against the use of picloram in areas where picloram is most likely to move through the soil into groundwater.

In the 1985 Standard spray drift droplet size and drift field studies were required. Data submitted in response to this requirement were not acceptable because experimental design was not according to current guideline requirements. The Agency is requiring that spray drift droplet size and drift field studies be submitted for picloram. These studies are required because of the following picloram concerns: phytotoxicity, aerial application, and likely exposure to nontarget plants. The droplet spectrum study is performed to reflect the nozzle and other equipment types to be used in application of picloram to pasture/rangeland, rights-of-way and forestry uses. The spray drift field evaluation is being performed to reflect the application equipment, use patterns, and typical locations of use, which includes different weather factors in applications of picloram for these uses.

Endangered Species

Because of the demonstrated toxicity to nontarget plant species and the intended use pattern, picloram has been identified by the U.S. Fish and Wildlife Service as being likely to jeopardize endangered plant species when used on pastures/rangeland and forests. Based on this determination the U.S. Fish and Wildlife Service specified reasonable and prudent alternatives to avoid jeopardizing the continued existence of the species by these uses. EPA is working with the Fish and Wildlife Service and other Federal and State Agencies to implement the alternatives in a technically sound manner.

Because of picloram low toxicity to avian species, aquatic species, and mammals, endangered animal species are not expected to be jeopardized by the use of picloram. Some aquatic invertebrates may be jeopardized.

I. PRODUCT CHEMISTRY

The Agency has determined that product chemistry data for all technicals and MPs must be submitted for each pesticide because new requirements have been introduced and previously submitted data must be updated. Therefore, most of the product chemistry data for the technical deemed acceptable in the 1985 Standard must be updated and submitted. Much of the data submitted recently are acceptable for the K salts. Refer to the data tables for detailed requirements.

No data are available for the IOE, TIPA, TEA, or IPA forms of picloram. These data are required. Refer to the data tables for detailed requirements.

J. PESTICIDE INCIDENT REPORTS

The Agency has received a number of pesticide incident reports with respect to crop and other nontarget plant damage. The damage was attributed to one or more of these factors: soil residues, drift from aerial or ground application, runoff after heavy rains, movement in irrigation water, or movement in groundwater.

K. TOLERANCE ASSESSMENT

Tolerances have been established for residues of picloram from application of its acid form, it potassium salt form, its triethylamine or triisopropanalamine salt under 40 CFR 180.292. Food and feed additive tolerance have been established for picloram under 40 CFR 185.4850 and 186.4850. These sections replace the earlier 21 CFR 193.350 and 21 CFR 561.305 sections.

A Canadian tolerance has been established for barley at 1.0 ppm. This is not consistent with tolerances established. No other Canadian, Mexican, or Codex tolerances have been established for picloram.

Residue Data

The residue data reviewed in support of these tolerances, and the data gaps are discussed below.

1. In the 1985 Standard the nature of residue in plants was deemed to be adequately understood. Based on additional wheat metabolism data submitted in support of a request to increase tolerances in forage grasses the Agency has concluded that the nature of the residue of picloram in plants is not adequately understood. The available data fail to show the extent to which

residues of picloram and its metabolites are conjugated in plant tissues, and the portion of the residue accounted for by the metabolites remains to be quantified.

2. In the 1985 Standard additional data was required to define the nature of the residue in poultry. Based on a hen metabolism study submitted in response to that request the nature of the residue in poultry is adequately understood. Data depicting the metabolism of picloram in hens indicate that 99.9 percent of the recovered radioactivity was found in the excreta, and 98 to 99 percent of these ^{14}C residues were characterized by HPLC as picloram. GC-MS analysis of the radioactive fractions of the excreta extract confirmed the identity of the residue as picloram. The radioactivity in the kidney was also identified as picloram (91-94%); an unidentified peak contained up to 6 percent of the ^{14}C-activity in the kidney. In the liver extract, 82 to 88 percent of the radioactivity was characterized as picloram; an unidentified compound accounted for 7 to 9 percent. Of the radioactivity recovered in egg white, picloram accounted for 81 to 78 percent and several minor peaks each accounted for 2 to 5 percent of the ^{14}C residues. These data were found to satisfy the requirements for metabolism of picloram in poultry requested in the 1985 Standard.

3. In the 1985 Standard additional data were required to define the nature of the residue in ruminants. Data submitted in response to that Standard were not adequate to define the nature of residue in ruminants, because complete characterizations of ^{14}C-residues in milk and ruminant tissues have not been reported. Data are required for the impurity, HCB. A determination of whether this impurity must be included in the tolerance expressions will await submission and review of data. Data for HCB were not required in the 1985 standard.

4. Picloram has not been analyzed by any of the multiresidue methods published in PAM Vol. I, Appendix II - Multiresidue Method Testing; these data must be submitted. Analytical methodology for the quantification of residues of the impurity HCB in or on raw agricultural commodities (RACs) and processed products are also needed. The methodology submitted for HCB must be capable of detecting this chemical at levels of $\leq$ 1 ppb. Multiresidue method testing is a new requirement since issuance of the 1985 Standard.

5. In the 1985 Standard storage stability data were required for grain crops of wheat, barley, oats, flax and forage grasses. Data submitted in response to that standard indicate residues of picloram are stable in grasses, wheat and barley grains, straw and green forages. Storage stability data on other crops were not submitted in time for inclusion in this standard. Residue data submitted for HCB must be supported by storage stability data.

6. Additional residue data for picloram in wheat grain forage and straw are required. A processing study in wheat grain is needed in order to determine whether residues of picloram concentrate in wheat. The residue data should adequately represent the full geographic range of states in which the use is registered. These data must be accompanied by storage stability data. A pre-harvest interval (PHI) must be proposed for wheat and submitted data must support this interval. An appropriate tolerance must be proposed for wheat hay based on supporting residue data. The requirements for a PHI or hay tolerances were not required by the 1985 standard. Tolerances for oat and barley hay must be proposed.

7. Data for residues of HCB in wheat grain, forage and straw are required. This data should be reported along with analysis of each formulation for HCB. If detectable, weathered residues of HCB are observed on wheat grain a processing study will be required to determine whether HCB residues concentrate in milling fractions of wheat. Residue data for HCB was not required by the 1985 standard.

8. The data reviewed by the 1985 Standard indicated that the established tolerance of 80 ppm on forage grasses was not adequate. Data submitted in a petition to increase the tolerance for forage grasses to 225 ppm were not adequate because data did not adequately represent the full geographical ranges of states where this use pattern is registered. Additional residue data for picloram are required. A tolerance for grass hay must be proposed and supported by data. All product labels with the pasture and rangeland use must be modified to include a maximum number of applications per season or a maximum seasonal rate. Required residue data must reflect the maximum rate or maximum number of applications. The 1985 standard did not require a hay tolerance or label revision.

9. Data for residues of HCB in pasture and rangeland grasses and their hays are required. This data should be reported with analyses of each formulation for HCB. The 1985 standard did not require HCB testing.

10. Additional residue data are required for flax depicting levels of HCB in flaxseed or flax straw. HCB testing was not required by the 1985 Standard.

11. The established tolerances for raw agricultural commodities, animal commodities, food and feed items will be evaluated upon receipt of requested data.

Dietary Exposure

The Agency has established a provisional acceptable daily intake (PADI, R.F.D.) at 0.07 mg/kg/day based on a 6-month dog feeding study (NOEL of 7.0 mg/kg/day) using a safety factor of 100. The theoretical maximum residue contribution (TMRC) is calculated to be 0.001840 mg/kg/day, which utilizes 2.6 percent of the PADI.

IV. REGULATORY POSITIONS AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALE

1. None of the risk criteria in 40 CFR 154.7 have been exceeded for picloram. Therefore, no referral to Special Review is being made at this time.

Rationale: A review of the available information indicates that none of the risk criteria for adverse effects in 40 CFR 154.7 have been exceeded. Available data indicate that picloram does not pose a risk of serious injury to humans, avian species, or aquatic organisms. Refer to Agency assessment for discussion of available data.

2. The Agency will continue to require that EPs containing picloram retain the "Restricted Use" classification and the groundwater advisory against the use of picloram on well-drained soils. Refer to Required Labeling section for wording.

Rationale: Picloram has been found in groundwater (7 States have reported detections of picloram in groundwater; Kansas, Missouri, North Dakota, New York, South Dakota, Wisconsin, and Minnesota) and shown to be phytotoxic to nontarget plant species. Available data indicate that picloram is intermediately to very mobile in most soils and degrades very little under irradiation, anaerobic, or aerobic conditions indicating a potential to contaminate groundwater. Refer to Agency Assessment for discussion of data. The precaution advisory against the use of picloram on well-drained soils will help reduce the risk of phytotoxicity by advising against use of picloram in areas where it is most likely to move through the soil into the groundwater. Refer to History and Agency Assessment sections for detailed discussion. Refer to Required Labeling section for appropriate statements.

3. The Agency is requiring the rat and mouse oncogenicity studies be repeated using Osborne-Mendel rats and $B_6C_3F_1$ mice of both sexes using a commercially available technical grade picloram uncontaminated with HCB.

Rationale: A study using Osborne-Mendel rats showed an oncogenic effect (neoplastic nodules) in the liver of females at the highest dose. The test material for the rat study was a technical grade picloram contaminated with a high level of HCB, contaminant know to product liver tumors in some strains of rats making it difficult to determine if the oncogenic effect is from the HCB or the picloram. The mouse study showed no oncogenic effects but was questionable as to whether an MTD was reached. EPA classified picloram as Group D oncogen (not classified as to human carcinogenicity).

Because of deficiencies in the oncogenicity studies they should be repeated using the same strains of test animals and technical picloram uncontaminated by potentially tumorigenic levels of HCB.

4. The Agency has determined that acute, subchronic feeding, teratology and mutagenicity studies are needed for the organic esters and amines of picloram in addition to the complete toxicological testing of the acid and/or K salt.

Rationale: In the 1985 Standard, the Agency considered the different forms of picloram to be toxicologically similar and required testing on the acid form to fulfill data requirements for all forms of picloram. For consistency in evaluation of chemicals with several forms, the Agency now considers salts, organic esters, and amines to be significantly different and to behave differently under testing unless data are available to show otherwise. The Agency expects the acid and K salt to behave similarly. Because the ester and the amines have a chemical moiety not present in the acid or K salt, the remaining organic esters and amines are significantly different, they may have different qualitative/ quantitative toxicological properties. To evaluate applicator risk and to determine if these organic esters and amines differ significantly from the acid and each other, basic toxicology testing is required. Refer to data tables and Agency assessment for specific requirements.

5. The Agency will continue to require manufacturers to limit the level of HCB in the technical to a maximum of 200 ppm.

Rationale: Technical picloram is contaminated with HCB which has been shown to be a carcinogen in several species of rodent. A risk assessment performed by the Agency indicated that risk estimates based on this level are acceptable. Refer to Agency assessment for additional discussion.

6. The Agency is requiring nitrosamine testing for the tertiary amine and alkanoloamine forms of picloram. The level of nitrosamines permitted in these forms is a maximum of 1 ppm. This position differs from the 1985 standard which limited the nitrosamine level to 1 ppm in the technical only.

Rationale: Nitrosamines may be a potential contaminant of the various amines used to produce the amine salts of picloram. This chemical is regulated under a rule which requires testing to show that a level of 1 ppm of nitrosamine contamination is not exceeded. Refer to 45 FR 42854 for discussion. Testing requirements are discussed in the product chemistry data tables.

7. The Agency is requiring that a prospective groundwater monitoring study be submitted for picloram.

Rationale: Picloram has been identified as a chemical with potential to contaminate groundwater. This study is needed to fully assess picloram's groundwater contamination hazard. A retrospective study was required by the 1985 Standard. The Agency approved a request to convert the retrospective study to a prospective study.

8. The Agency is requiring that Tier II phytotoxicity testing be performed with technical picloram, K salt, and the IOE, TIPA, TEA, and IPA forms of picloram.

Rationale: Picloram is a herbicide and has been shown to be phytotoxic to nontarget plants. Tier I phytotoxicity testing was required under the 1985 Standard. The data submitted did not satisfy the requirements. Additional Tier I phytotoxicy is not required because the Agency is requiring Tier II testing to fully assess picloram's phytoxicity. Data are required on all forms of picloram because no comparative studies are available.

9. The Agency is requiring that droplet size spectrum and drift field evaluation data be submitted for picloram. These studies were required by the 1985 Standard.

Rationale: The data submitted in response to the 1985 standard was not acceptable because experimental design was not in accordance with the 1985 Guidelines. These data are required because of the chemical's phytotoxicity, its method of application (aerial), and the exposure of off-site wildlife and plants to picloram. The droplet spectrum study is to be performed to reflect the nozzle and other equipment types to be used in the application of picloram to pasture/rangeland, rights of way and forestry uses, the spray drift evaluation is to be performed to reflect the application equipment, use pattern, and typical locations of use which includes different weather factors, in the application of picloram for these uses.

10. The Agency is requiring that end-use product labels contain language relevant to spray drift control. This position remains unchanged from the 1985 standard. Refer to labeling section for statements.

Rationale: The Agency has received a number of pesticide incident reports with respect to loss of economically important crops and other nontarget plant damage.

11. The Agency is requiring that additional residue data be submitted for wheat grain, forage, straw and processed fractions of wheat. This data must adequately represent the full geographical range of usage and must include data depicting residue levels of and analyses of HCB. These data must be analyzed by current or proposed enforcement methods capable of detecting HCB levels $\leq$ 1 ppb. A PHI must be proposed and supported by data. All residue data must be supported by storage stability data. No data are required for barley or oats.

Rationale: The residue data required by the 1985 Standard were primarily storage stability data. These data were received and acceptable. Residue data required in 1985 did not include geographical representation or HCB testing. These data are now required to access the adequacy of established tolerances. Additional data are not required for oats and barley since data submitted for wheat will support tolerances for wheat and barley.

12. The Agency is requiring that additional residue data be submitted for forage grasses and hay. These data must represent the geographical range of usage and report levels of HCB along with analysis for HCB. Labels must be amended to reflect the maximum application per season or maximum application rate per season. The required residue data must reflect the maximum rate or maximum number of applications per season.

Rationale: Data reviewed for 1985 Standard indicated that the established tolerance for forage grasses was not adequate. Data submitted to support an increase in tolerance did not adequately represent the geographical range of this use pattern. Residue data required in 1985 did not include data to represent the geographical range or require HCB testing. These data are now required to support the proposed tolerances.

13. The Agency is requiring that additional residue data be submitted for flax and flaxseed.

Rationale: Residue data required by the 1985 Standard did not include residue testing for HCB. These data are required to fully assess the established tolerances for flax.

14. The Agency is requiring that additional residue data be submitted for grass hay and wheat hay and that appropriate tolerances be proposed for wheat, oat, barley, and grass hay.

Rationale: No residue data are available for hay and no tolerances have been established.

15. The Agency is requiring that additional plant metabolism data be submitted providing complete identification and quantitation of all terminal residues.

Rationale: In the 1985 Standard the nature of the residue in plant was adequately defined. Additional metabolism data submitted in support of the request to increase tolerances for forage grasses failed to show the extent to which residue of picloram and its metabolites conjugate in plant tissues, and the portion of the residue accounted for by the metabolites remains to be quantified. No data are available for residues of HCB should be included in the tolerance expression.

16. The Agency is requiring that further metabolism data be submitted to define the nature of the residue in animals. These data are required on ruminants. These data must include testing for HCB. No additional poultry metabolism testing is required.

Rationale: Data submitted in response to the 1985 Standard adequately define the nature of residue in poultry so no further poultry data are required. Refer to Residue Chemistry Section of Tolerance Assessement for discussion. Data submitted in response to the 1985 Standard for ruminants did not adequately define the nature of the residue in ruminants because complete characterizations of 14C residues in milk and ruminant tissues were not reported and HCB was not tested for. HCB testing was not required by the 1985 Standard.

17. The Agency is not requiring reentry data or intervals at this time. Reentry intervals or data were not required by the 1985 standard.

Rationale: Reentry data or intervals are not required for picloram because cultural practices for existing uses indicate little likelihood that field workers would be exposed to acutely toxic levels of picloram after agricultural treatment. Although the technical (free acid) form of picloram is placed in Toxicity Category I based on inhalation, reentry intervals are not needed because there are no products currently registered containing the free acid form of picloram.

18. The U.S. Fish and Wildlife Service has determined that certain uses of picloram may jeopardize the continued existence of endangered species or critical habitat of certain endangered species. EPA is developing a program to reduce or eliminate exposure to these species to a point where use does not result in jeopardy, and will issue notice of any necessary labeling revisions when the program is developed.

Rationale: In May 1987, EPA issued PR Notices 87-4 and 87-5 in response to OES findings that certain pesticides, including this chemical, jeopardized the continued existence of endangered species. Those PR Notices directed registrants to add labeling to their products which referred users to additional information that, in turn, explained limitations on use of the pesticide within the range of jeopardized endangered species. Subsequent to issuance of these PR Notices, EPA identified a number of significant technical errors and inconsistencies in the information to which users would have been referred. Therefore, on January 26, 1988 the Agency issued PR Notice 88-1 which withdrew PR Notices 87-4 and 87-5 pending development of a more focused program to protect endangered species.

EPA is working to correct these errors prior to requiring labeling to protect endangered species. When that program is fully developed, notice of any labelng necessary to protect endangered species will be issued.

19. The Agency is requiring that labeling for all end-use and manufacturing use products determined to be skin sensitizers by the results of acute toxicology data include the labeling statement "This product may cause allergic skin reaction after multiple exposures."

Rationale: Acute toxicology data reviewed (refer to Agency Assessment) indicate that some forms of picloram are skin sensitizers and require that the statement "This product may cause allergic skin reaction after multiple exposures." appear on the label.

20. The Agency will not approve any significant* new food uses for picloram until required residue chemistry and toxicology data are available to assess existing and new uses.

Rationale: It is Agency policy not to establish significant new uses where major toxicology and residue chemistry data gaps exist. When additional data are evaluated the Agency will determine whether significant new uses may be established.

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*"Significant new uses" is defined in 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will consider as significant an increase in the TMRC of > 1 percent.

21. The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies.

Part 158 Subpart C - Product Chemistry - Concerns about hazards presented by impurities (HCB and nitrosamines).

61-2 - Description of Beginning Materials and Manufacturing Process
61-3 - Discussion of Formation of Impurities
62-1 - Preliminary Analysis
62-2 - Certification of Limits
62-3 - Analytical Methods to Verify Certified Limit

158.340 - Residue Chemistry - To determine which metabolites (plant or animal) must be tested for in the field trials and processing studies.

171-4 - Plant Metabolism
171-4 - Animal Metabolism
171-4 - Residue Analytical Methods

Part 158.315 - Toxicology - To fully determine toxicological potential of picloram.

81-1
thru
81-6 - Acute Toxicity on esters and amines of picloram.
82-1 - 90-Day Feeding (rodent and nonrodent) on esters and amines of picloram - Needed to determine if chronic testing is required.

82-2 - 21-Day Dermal - Needed to determine if additional testing is required.
83-2 - Oncogenicity (rat and mouse)
83-3 - Teratology, both species
83-4 - Reproduction
84-2 - Mutagenicity

158.290 - Environmental Fate - To fully define potential of picloram to contaminate groundwater.

158-75 - Groundwater Monitoring Data

158.440 - Spray Drift - To determine potential phytotoxicity to nontarget plants from drift.

22. While data gaps are being filled, currently registered MPs and EPs containing picloram may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. Additionally, registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA sections 3(c)(2)(B) and 3(c)(7) the Agency may elect not to cancel or withhold registrations if data are missing or inadequate. Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain picloram bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain this pesticide. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade, and manufacturing-use products containing this pesticide provided that the product labeling bears appropriate precautionary statements for actue toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products must be labeled for formulation into end-use products only for the commodities listed below. The EPA Index to Pesticide Chemicals (for availability, see page 1) lists all registered uses, as well as approved maximum application rates and frequencies.

- Terrestrial, non-domestic, food uses on:

  small grains, flax, pastures and rangeland grasses

- Terrestrial, non-domestic, non-food uses on:

  noncrop agricultural areas, uncultivated agricultural areas, industrial sites, rights-of-way.

- Forestry Uses on:

  forest lands site preparation and forest trees.

- Aquatic nonfood use on:

  drainage ditchbanks

D. Labeling

In order to remain in compliance with FIFRA, products must bear appropriate labeling as specified in 40 CFR 156.10 and this standard, or must be revised to conform to those specifications. Appendix II contains information on label requirements.

No pesticide prodct containing this pesticide may be released for shipment by the registrant after September 30, 1989, unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing this pesticide may be distributed or sold after September 30, 1990 unless the product bears an amended label which complies with the requirements of this standard.

The following specific information must appear on the labeling in order for products to remain in compliance with FIFRA.

INGREDIENT STATEMENT

The ingredient statement for products must list the active ingredient as:

INGREDIENT STATEMENT

ACTIVE INGREDIENT:
Picloram (4-amino-3,5,6-trichloropicolinic acid) . . . . ___%
INERT INGREDIENTS: . . . . ___%

ACTIVE INGREDIENT:
Picloram (4-amino-3,5,6-trichloropicolinic acid), as the potassium salt . . . . ___%
INERT INGREDIENTS: . . . . ___%

ACTIVE INGREDIENT:
Picloram (4-amino-3,5,6-trichloropicolinic acid), as the triethylamine salt . . . . ___%
INERT INGREDIENTS: . . . . ___%

ACTIVE INGREDIENT:
Picloram (4-amino-3,5,6-trichloropicolinic acid), as the triisopropanolamine salt . . . . ___%
INERT INGREDIENTS: . . . . ___%

ACTIVE INGREDIENT:
Picloram (4-amino-3,5,6-trichloropicolinic acid), as the isooctyl ester . . . . ___%
INERT INGREDIENTS: . . . . ___%

ACTIVE INGREDIENT:
Picloram (4-amino-3,5,6-trichloropicolinic acid), as the isopropanolamine . . . . ___%
INERT INGREDIENTS: . . . . ___%

Manufacturing-Use Products

1. The following statements must appear directly beneath the product name:

A Herbicide For Formulating Use Only.

Formulators using this product are responsible for obtaining EPA registration of their formulated products.

For formulation into end-use herbicide products intended only for the following uses

Picloram, potassium salt: Terrestrial food crop use on small grains, flax, pastures, and rangeland grasses;

Terrestrial noncrop site on noncrop agricultural areas and rights-of-way;

Forestry use on forest lands site preparation.

Picloram, isooctyl ester: Terrestrial nonfood crops use on industrial sites and rights-of-way;

Forestry use on forest trees site preparation.

Picloram, triisopropanolamine salt: Terrestrial food crop use on small grains and pastures and rangeland;

Terrestrial nonfood crop use on uncultivated agricultural areas, rights-of-way, and industrial sites;

Aquatic nonfood crop use on drainage ditchbanks;

Forestry use on forest trees.

Picloram, triethylamine salt: Terrestrial food crop use on pastures and rangelands.

2. The following environmental hazards statement labeling is specified for all MPs.

> Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

3. All MPs that are dermal sensitizers based on acute toxicology studies must include the following precautionary statement on their labels:

> This product may cause allergic skin reaction after multiple exposures.

End-Use Labeling

1. Restricted Use Statement

The following Restricted Use statement must appear on the front panel of all picloram EPs.

RESTRICTED USE PESTICIDE

Due to Groundwater Contamination.
Toxic to Nontarget Plants

> For retail sale to and use only by certified applicator or persons under their direct supervision and only for those uses covered by the certified applicator's certification. Commercial certified applicators must also ensure that all persons involved in these activities are informed of the precautionary statements.

2. The following groundwater advisory statement must appear on the label of an EP containing picloram.

> Picloram is a chemical which can travel (seep or leach) through soil and under certain conditions contaminate groundwater which may be used for irrigation and drinking purposes. Users are advised not to apply picloram where soils have a rapid to very rapid permeability throughout the profile (such as loamy sand to sand) and the water table of an underlying aquifer is shallow, or to soils containing sinkholes over limestone bedrock, severely fractured surfaces, and substrates which would allow direct introduction into an aquifer. Your local agricultural agencies can provide further information on the type of soil in your area and the location of groundwater.

3. The following revised Environmental Hazards statement must appear on the label of EPs containing picloram.

> Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters.

4. All EPs that are dermal sensitizers based on acute toxicology data must include the following precautionary statements on their labels:

> This product may cause allergic skin reaction after multiple exposure.

5. All end-use products must include the following statement pertaining to drift on their labels:

> "Do not make application when circumstances favor movement from treatment site."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

   1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

   2. The data requirements listed in Tables A and B.[2]

   3. The labeling requirements specified for manufacturing use products in Section IV.

   4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

   1. The data requirements listed in Table A.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end-use products at this time. Therefore, most Registration Standards do not contain a Table C.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption,[3] the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person

who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Develop-ment of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

[Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec.

3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the time-frames for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing

stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6. (cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: [Name of chemical] Registration Standard

All submittals in response to this Registration Standard are non-fee items, including 90-day responses, protocols and waiver requests, data, and revised labeling. Submittals must be clearly identified as being in response to the Registration Standard. Under no circumstances may Registration Standard responses be combined with other types of filings for which fees are required.

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

   a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

   b. Confidential Statement of Formula (EPA Form 8570-4).

   c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

   a. Application for Pesticide Registration (EPA Form 8570-1).

   b. Two copies of any required product-specific data (See Table B).

   c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

   d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

Table A
Generic Data Requirements for Picloram

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission
§158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity and Disclosure of Ingredients	Acid-TGAI	All	No	NR[2]	No	
	K Salt		No		Yes[3]	6 Months
	TIPA		No		Yes[4]	6 Months
	IOE		No		Yes[4]	6 Months
	TEA		No		Yes[4]	6 Months
	IPA		No		Yes[4]	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	Acid-TGAI	All	Yes	00115556	No	
	K Salt		No		Yes[5]	6 Months
	TIPA		No		Yes[5]	6 Months
	IOE		No		Yes[5]	6 Months
	TEA		No		Yes[5]	6 Months
	IPA		No		Yes[5]	6 Months
61-3 - Discussion of Formation of Impurities	Acid-TGAI	All	Yes	00154235	No	
	K Salt		Yes	00154235	No	
	TIPA		No		Yes[6]	6 Months
	IOE		No		Yes[6]	6 Months
	TEA		No		Yes[6]	6 Months
	IPA		No		Yes[6]	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	Acid-TGAI	All	Yes	00154235	No	
	K Salt		Yes	00154235	No	
	TIPA		No		Yes[7]	12 Months
	IOE		No		Yes[7]	12 Months
	TEA		No		Yes[7]	12 Months
	IPA		No		Yes[7]	12 Months

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance1/	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission
§158.120 Product Chemistry						
Analysis and Certification of Product Ingredients (Cont'd)						
62-2 - Certification of Limits	Acid-TGAI	All	No	NR2/	No	
	K Salt		No		Yes8/	12 Months
	TIPA		No		Yes8,9/	12 Months
	IOE		No		Yes8/	12 Months
	TEA		No		Yes8,9/	12 Months
	IPA		No		Yes8/	12 Months
62-3 - Analytical Methods to Verify Certified Limit	Acid-TGAI	All	Yes	00154235 40588501	No	
	K Salt		Yes	00154235 40588501	No	
	TIPA		No		Yes10/	12 Months
	IOE		Yes	00154235 40588501	No	
	TEA		No		Yes10/	12 Months
	IPA		Yes	00154235 40588501	No	
Physical and Chemical Characteristics						
63-2 - Color	Acid-TGAI	All	No	N/A11/	Yes	6 Months
	K Salt		Yes	40588501	No	
	TIPA		No		No12/	
	IOE		No		No12/	
	TEA		No		No12/	
	IPA		No		No12/	

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance[1]/	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission
§158.120 Product Chemistry						
Physical and Chemical Characteristics (Cont'd)						
63-3 - Physical State	Acid-TGAI	All	No	N/A[11]/	Yes	6 Months
	K Salt		Yes	40588501	No	
	TIPA		No		No[12]/	
	IOE		No		No[12]/	
	TEA		No		No[12]/	
	IPA		No		No[12]/	
63-4 - Odor	Acid-TGAI	All	No	N/A[11]/	Yes	6 Months
	K Salt		Yes	40588501	No	
	TIPA		No		No[12]/	
	IOE		No		No[12]/	
	TEA		No		No[12]/	
	IPA		No		No[12]/	
63-5 - Melting Point	Acid-TGAI	All	No	N/A[11]/	Yes	6 Months
	K Salt		Yes	40588501	No[13]/	
	TIPA		No		No[12]/	
	IOE		No		No[12]/	
	TEA		No		No[12]/	
	IPA		No		No[12]/	
63-6 - Boiling Point	Acid-TGAI	All	No	N/A[11]/	No[14]/	
	K Salt		Yes	40588501	No	
	TIPA		No		No[12]/	
	IOE		No		No[12]/	
	TEA		No		No[12]/	
	IPA		No		No[12]/	

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission
§158.120 Product Chemistry						
Physical and Chemical Characteristics (Cont'd)						
63-7 - Density, Bulk Density, or Specific Gravity	Acid-TGAI	All	No	N/A[11]	Yes	6 Months
	K Salt		Yes	40588501	No	
	TIPA		No		No[12]	
	IOE		No		No[12]	
	TEA		No		No[12]	
	IPA		No		No[12]	
63-8 - Solubility	Acid-TGAI	All	No	N/A[11]	Yes	6 Months
	K Salt		No		No[14]	
	TIPA		No		Yes[15]	6 Months
	IOE		No		Yes[15]	6 Months
	TEA		No		Yes[15]	6 Months
	IPA		No		Yes[15]	6 Months
63-9 - Vapor Pressure	Acid-TGAI or PAI		No	N/A[11]	Yes	6 Months
	K Salt		No		No[14]	
	TIPA		No		Yes[15]	6 Months
	IOE		No		Yes[15]	6 Months
	TEA		No		Yes[15]	6 Months
	IPA		No		Yes[15]	6 Months
63-10 - Dissociation Constant	Acid-TGAI or PAI		No	N/A[11]	Yes	6 Months
	K Salt		No		No[14]	
	TIPA		No		Yes[15]	6 Months
	IOE		No		Yes[15]	6 Months
	TEA		No		Yes[15]	6 Months
	IPA		No		Yes[15]	6 Months

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission
§158.120 Product Chemistry						
Physical and Chemical Characteristics (Cont'd)						
63-11 - Octanol/Water Partition Coefficient	Acid-PAI	All	No	N/A[11]	Yes	6 Months
	K Salt		No		No[14]	
	TIPA		No		Yes[15]	6 Months
	IOE		No		Yes[15]	6 Months
	TEA		No		Yes[15]	6 Months
	IPA		No		Yes[15]	6 Months
63-12 - pH	Acid-PAI		No	N/A[11]	Yes[16]	6 Months
	K Salt		Yes	40588501	No	
	TIPA		No		No[12]	
	IOE		No		No[12]	
	TEA		No		No[12]	
	IPA		No		No[12]	
63-13 - Stability	Acid-TGAI	All	No	N/A[11]	Yes	6 Months
	K Salt		No		No[14]	
	TIPA		No		Yes[12]	6 Months
	IOE		No		Yes[12]	6 Months
	TEA		No		Yes[12]	6 Months
	IPA		No		Yes[12]	6 Months
63-14 - Oxidizing or Reducing Action	Acid-TGAI	All	No		No[2]	
	K Salt		Yes	40588501	No	
	TIPA		No		No[12]	
	IOE		No		No[12]	
	TEA		No		No[12]	
	IPA		No		No[12]	

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission
§158.120 Product Chemistry						
Physical and Chemical Characteristics (Cont'd)						
63-15 - Flammability	Acid-TGAI	All	No		No[2]	
	K Salt		Yes	40588501	No	
	TIPA		No		No[12]	
	IOE		No		No[12]	
	TEA		No		No[12]	
	IPA		No		No[12]	
63-16 - Explodability	Acid-TGAI	All	No		No[2]	
	K Salt		Yes	40588501	No	
	TIPA		No		No[12]	
	IOE		No		No[12]	
	TEA		No		No[12]	
	IPA		No		No[12]	
63-17 - Storage Stability	Acid-TGAI	All	No		No[2]	
	K Salt		Yes	40588501	No	
	TIPA		No		No[12]	
	IOE		No		No[12]	
	TEA		No		No[12]	
	IPA		No		No[12]	
63-18 - Viscosity	Acid-TGAI	All	No		No[2]	
	K Salt		No		Yes[17]	6 Months
	TIPA		No		No[12]	
	IOE		No		No[12]	
	TEA		No		No[12]	
	IPA		No		No[12]	

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission
§158.120 Product Chemistry						
Physical and Chemical Characteristics (Cont'd)						
63-19 - Miscibility	Acid-TGAI	All	No		No[2]	
	K Salt		No		Yes[18]	6 Months
	TIPA		No		No[12]	
	IOE		No		No[12]	
	TEA		No		No[12]	
	IPA		No		No[12]	

1/Test substance: 88% unregistered technical = acid; 34.7% FI + Potassium salt of picloram = K Salt; triisopropanolamine salt of picloram = TIPA; Isooctyl ester of picloram = IOE; Triethylamine salt of picloram = TEA; and isopropanol amine salt of picloram = IPA.

2/Data not required for unregistered technical.

3/Nominal concentrations for active ingredient and each intentionally added inert must be submitted. The name and upper certified limit must be provided for each impurity or group of impurities for which a certified limit is required. This information must be submitted on EPA Form 8570-4.

4/The product name, chemical name, nominal concentration, certified limits, CAS Registry Number, and purpose of each intentionally added inert must be provided for the TIPA, IOE, TEA, and IPA end-use products (EPs). The name and upper certified limit must be provided for each impurity or group of impurities for which a certified limit is required for all EPs produced by an integrated formulation system. This information must be submitted on EPA Form 8570-4.

5/Complete information must be submitted for the K salt formulation intermediate (FI) and all EPs produced by an integrated formulation system regarding the nature of the process (batch or continuous), the relative amounts of beginning materials, the chemical equation for each reaction, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, supplier, or producer of each beginning material used in the manufacture of the EPs produced by an integrated formulation system, and information regarding the properties of each beginning material used in manufacture of the FI and EPs produced by an integrated formulation system must be provided.

6/A detailed discussion of all impurities that are or may be present at $\geq 0.1\%$ in all EPs produced by an integrated formulation system, based on knowledge of beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

Table A
Generic Data Requirements for Picloram (Cont'd)

Footnotes (Cont'd)

7/Five or more representative samples of each of the EPs produced by an integrated formulation system must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

8/Upper and lower limits for the active ingredient and each intentionally added inert and upper limits for each impurity present at $\geq$ 0.1% (w/w) and each additional "toxicologically significant" impurity present at < 0.1% (w/w) are required for the FI and all EPs produced by an integrated formulation system. Limits must be certified, and an explanation of how each certified limit was established must be provided. Certification will be specifically required for the toxicologically significant impurity hexachlorobenzene (HCB). Certification must be submitted on EPA Form 8570-4.

9/Validated certified limits for N-nitroso contaminants are required for all EPs that contain tertiary alkanolamines or tertiary amines. The nitrosoamines must be identified in six samples of each product; two samples might be analyzed shortly after production, 3 months after production, and 6 months after production. A method of sensitivity to 1 ppm of N-nitroso contaminants must be used.

10/Analytical methods must be provided to determine N-nitrosoamines in all EPs containing tertiary alkanolamines or tertiary amines. The method must be accompanied by validation studies indicating its accuracy and precision.

11/Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

12/These data are not required for EPs produced by an integrated formulation system.

13/Data are not required for manufacturing use products (MPs).

14/Data are not required because TGAI is a solid at room temperature.

15/As required by 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, data using a pure (PAI) form of TIPA, IOE, TEA, AND IPA must be submitted.

16/Data are required on pH if the test substance can be diluted or dispersed in water.

17/Data on miscibility are required if the product is a liquid.

18/Data on miscibility are required if the product is an emulsifiable liquid and it is to be diluted with petroleum solvents.

Table A
Generic Data Requirements for Picloram

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[1/]
§158.240 Residue Chemistry						
171-2 - Chemical Identity[2/]		A				
171-3 - Directions for Use		A				
171-4 - Nature of Residue (Metabolism) - Plants	PAIRA	A	Partially	00037880,00041136, 00059411,00111527, 00157171	Yes[3,4,5/]	18 Months
171-4 - Nature of Residue (Metabolism) - Livestock	PAIRA and plant metabolites	A	Partially	00023105,00041125, 00161306,00163216	Yes[6,7,8,9/]	18 Months
171-4 - Residue Analytical Methods	TGAI and metabolites	A	Partially	00026748,00026749, 00026750,00026751, 00026752,00026753, 00027288,00035959, 00045363,00045373, 00045374,00045375, 00045376,00045409, 00062818,00078483, 00085060,00111404, 00111407,00131364, 00132986,00156366	Yes[10,11,12/]	15 Months
171-4 - Storage Stability	TEP and metabolites	A	Partially	00164725,40082701, 40435601	Yes[13/]	15 Months

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[1]/
§158.240 Residue Chemistry						
171-4 - Magnitude of the Residue in Plants - Cereal Grains Group[14]/						
o Cereal Grains - Barley	TEP	A	Partially	00036168,00036170, 00036171,00045369, 00128714	Yes[15]/	18 Months
- Barley Milled Products	EP	A	No		Yes[15]/	24 Months
- Oats	TEP	A	Partially	00036168,00036170, 00036171,00045369, 00128714	Yes[16]/	18 Months
- Oat Milled Products	EP	A	No		Yes[16]/	24 Months
- Wheat	TEP	A	Partially	00036168,00036170, 00036171,00045369, 00128714	Yes[17]/	18 Months
- Wheat Milled Products	EP	A	No		Yes[18,19]/	24 Months
o Forage, Fodder and Straw of the Cereal Grains Group[20]/						

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[1/]
§158.240 Residue Chemistry						
171-4 - Magnitude of the Residue in Plants						
- Cereal Grains Group (Cont'd)						
- Barley Forage/Straw	TEP	A	Partially	00036168,00036170, 00036171,00128714	Yes[21/]	18 Months
- Oat Forage/ Straw	TEP	A	Partially	00036168,00036170, 00036171,00128714	Yes[22/]	18 Months
- Wheat Forage/ Straw	TEP	A	Partially	00036168,00036170, 00036171,00128714	Yes[23,24/]	18 Months
o Grass Forage, Fodder and Hay - Grasses	TEP	A	Partially	00062817,00108862, 00108864,00111404, 00111482,00111557, 00156366	Yes[25,26,27,28/]	18 Months
o Miscellaneous Commodities						
- Flaxseed	TEP	A	Partially	00085060	Yes[29/]	18 Months
171-4 - Magnitude of the Meat/Milk/Poultry/Eggs	TGAI or plant metabolites	A	Partially	00085060	Yes[30/]	18 Months

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1/Data must be submitted within the indicated timeframe, based on the date of this Guidance Document.

2/The same chemical identity data are required under 158.120, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.

3/Data depicting the distribution and metabolism of ring-labeled [^{14}C]picloram in or on wheat forage, grain, and straw are required. A completely characterized test substance representative of technical picloram (including impurities) used in commercial formulations must be applied at rates sufficiently high to permit characterization

Table A
Generic Data Requirements for Picloram (Cont'd)

Footnotes (Cont'd)

of ^{14}C-residues. The identities and quantities of residues, including conjugated residues, in or on mature plant parts must be determined in order to elucidate terminal residues. The registrant may partially satisfy these data requirements by providing additional data including but not limited to the following: (i) raw data needed to determine the percentage of the total radioactivity in each tissue recovered by HPLC (total extract volume, injection volume, total counts in each extract); (ii) the results of TLC analysis of the extracts to permit the identification of ^{14}C-residues in the conjunct peaks noted in the HPLC histograms; (iii) hydrolysis, extraction, *and TLC analyses of radioactivity* not extracted into sodium hydroxide or into ether; and (iv) data reflecting the extraction of plant samples with methanol (used to extract the free and conjugated metabolites of picloram as well as conjugated picloram in the previous study on wheat) and the subsequent identification and quantification of all terminal residues.

4/Representative samples from these studies must also be analyzed by current or proposed enforcement methods including Multiresidue Protocols I-IV to ascertain that all residues of concern are determined.

5/Residue data are required for the impurity hexachlorobenzene (HCB). If detectable levels of HCB are found, this impurity will be included in the tolerance expression for picloram.

6/Metabolism studies utilizing ruminants are required. Animals must be dosed orally for a minimum of 3 days with [^{14}C]picloram at a level sufficient to make residue identification and quantification possible. Milk must be collected twice a day during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and identity of residues must be determined in milk, liver, kidney, muscle, and fat. The registrant may partially satisfy these data requirements by providing additional data including but not limited to the following: (i) results of analyses of urine, feces, milk, and tissue extracts by TLC using mobile systems with different polarities in order to separate all possible residues; (ii) GC-MS chromatograms of radioactive residues isolated from milk and tissue samples; and (iii) identification of all peaks shown in the GC-MS analyses of urine and fecal extracts or GC-MS analyses of nonradioactive extracts to determine which peaks represent radioactive residues.

7/Samples from these studies must also be analyzed using current or proposed enforcement methods to ascertain that the methods are capable of adequately recovering and identifying all residues of toxicological concern.

8/Data depicting the nature of picloram residues in swine are also required if the required metabolism studies reveal that the metabolism of picloram in ruminants differs from that in rats.

9/Data are required for HCB. If detectable residues of HCB are observed in animal commodities, then this impurity will be included in the tolerance expression for picloram.

10/Representative plant samples, ruminant tissues, milk, and eggs bearing residues of picloram must be subjected to analysis by Multiresidue Protocols I, II, III, and IV in PAM Vol. I. These protocols are available from the National Technical Information Service under Order No. PB203734/AS.

11/The registrant must report the details of the method(s) used to quantitate HCB in plant commodities. The method(s) used must be capable of detecting HCB levels of ≤ 1 ppb. Data on recovery of HCB from fortified and apparent residues in or on untreated control samples must be submitted to validate the method(s).

Table A
Generic Data Requirements for Picloram (Cont'd)

Footnotes (Cont'd)

12/If the requested data on plant and ruminant metabolism indicate that residues of toxicological concern occur in plant commodities, ruminant tissues, or milk, methods for data collection and enforcement will be required. EPA has required, in the sections entitled "Nature of the Residue in Plants" and "Nature of the Residue in Animals" that representative samples from the metabolism studies be subjected to analyses using all current or proposed methods for data collection and enforcement, including Methods I, II, and III in the PAM, Vol. II, Pesticide Reg. Sec. 180.292.

13/Storage conditions and intervals must be submitted for all samples used to provide the residue data on picloram and HCB requested in this document. This information must be accompanied by data depicting the percent decline in residues under the storage conditions and for the intervals specified. Samples bearing field-weathered residues or fortified samples must be analyzed immediately after harvest or fortification and again after storage intervals that are equivalent to those reflected in all previously submitted and currently requested residue data. Storage conditions for the samples must reflect data submitted previously and in response to the requirements of this document. The storage intervals selected must allow for reasonable unforeseen delays in sample analysis.

14/A crop group tolerance is not appropriate at this time for the following reasons:

- Proposed use directions and appropriate supporting residue data must be submitted depicting picloram residues of concern in or on the additional crop group members corn (fresh sweet corn and dried field corn), rice, and sorghum.
- Additional data to support the established tolerances for residues of picloram in or on barley, oats, and wheat (refer to the "Wheat" section for details of the data requirements) must be submitted.

15/Residue and processing data required for wheat will be translated to barley.

16/Residue and processing data required for wheat will be translated to oats.

17/Data depicting picloram residues of concern in or on wheat grain harvested following a single application (made when the wheat plants have five leaves) of representative SC/L (potassium salt) and EC (triisopropanolamine salt) formulations (each applied in separate tests) at 0.02 lb ai/A, using ground and aerial equipment in separate tests. Residues of HCB in or on these samples must be reported along with the results of analyses for HCB level of each batch of formulation used in these tests. Tests using the SC/L formulation must be conducted in ID or MT, MN, OK, SD, and UT, and tests using the EC formulation must be conducted in MT, ND, and/or SD in order to adequately represent the areas in which these uses are registered.

18/A processing study depicting picloram residues of concern in middlings and in grain dust from the processing of wheat bearing measurable, weathered residues is required. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed.

19/If detectable weathered residues of HCB are found in or on wheat grain, a processing study depicting residues of HCB in milled products (bran, flour, middlings, and shorts), and in grain dust from the processing, will be required. Analyses for HCB levels must be reported for each formulation used to treat the grain used in these processing studies.

Table A
Generic Data Requirements for Picloram (Cont'd)

Footnotes (Cont'd)

20/A crop group tolerance is not appropriate at this time for the following reasons:

- o Proposed use directions and appropriate supporting residue data must be submitted depicting picloram residues of concern in or on the additional crop group members corn forage and fodder and the forage, hay, and straw of one other group member.
- o Additional data to support the established tolerances for residues of picloram in or on the forage and straw of barley, oats, and wheat (refer to the "Wheat Forage, Hay, and Straw" section for details of the data requirement) must be submitted.

21/Residue data required for wheat forage and straw will be translated to barley forage and straw.

22/Residue data required for wheat forage and straw will be translated to oat forage and straw.

23/Data depicting picloram residues of concern in or on wheat forage and straw harvested following a single application, made when the plants have five leaves of representative SC/L (potassium salt) and EC (triisopropanolamine salt) formulations (each applied in separate tests) at 0.02 lb ai/A, using ground and aerial equipment in separate tests must be submitted. Residues of HCB in or on these samples must be reported along with the results of analyses for HCB levels of each batch of formulation used in these tests. Tests using the SC/L formulation must be conducted in ID or MT, MN, OK, SD, and UT, and tests using the EC formulation must conducted in MT, ND, and/or SD in order to adequately represent the areas in which these uses are registered. The registrant must propose a PHI and the available data must reflect this interval.

24/An appropriate tolerance must be proposed and residue supporting data must be submitted for the raw agricultural commodity (RAC) wheat hay.

25/Data depicting picloram residues of concern in or on pasture and rangeland grasses and hay from grasses harvested at regular intervals following application of a representative P/T formulation of the potassium salt of picloram (each applied in separate tests) at 4 lb ai/A must be submitted. Residues of HCB in or on these samples must be reported along with the results of analyses for HCB levels of each batch of formulation used in these tests. Tests must be conducted in CA, CT, GA (representative of AL), HI, MO (representative of AR, IA, and KS), PA, (representative of OH and NJ), TN (representative of NC), and TX (representative of OK and NM) to adequately represent the areas in which this use is registered.

26/Data depicting residues of concern in or on pasture and rangeland grasses and hay from grasses harvested on the day of application of a representative SC/L formulation of the potassium salt of picloram (applied by aerial and ground equipment in separate tests) at 4 lb ai/A must be submitted. Tests must be conducted in NE (also representing IA, MO, SD, and WY). Also, data must be submitted reflecting application at 2 lb ai/A; these tests must be conducted in MT (representing ID and ND), and AZ or UT (representating NV) to adequately represent the States in which this formulation class is registered. Residues of HCB in or on these samples must be reported along with the results of analyses for HCB level of each batch of formulation used in these tests.

27/Data depicting picloram residues of concern in or on pasture and rangeland grasses and grass hay harvested on the day of application of the 0.54 lb/gal EC formulation at 0.54 ai/A, in 10 gal of oil-water using ground equipment, and in 1 gal using aerial equipment; finished sprays containing 0.5% of an agricultural surfactant must be submitted. The tests must be conducted in TX which is representative of the area in which this use is registered (NM, OK, and TX).

Table A
Generic Data Requirements for Picloram (Cont'd)

Footnotes (Cont'd)

Residues of HCB in or on these samples must be reported along with the results of analyses for HCB level of each batch of formulation used in these tests.

28/The registrant must amend all pertinent product labels to include a maximum number of applications per season or a maximum seasonal application rate. The requested residue data must reflect the proposed maximum rate or number of applications.

29/Data depicting residues of HCB in or on flaxseed and flax straw harvested following application of the 2 lb/gal SC/L formulation of the potassium salt of picloram at 0.016 lb ai/A, made when plants are 3 inches tall must be submitted. Each batch of product used in the tests must be analyzed for HCB level and the results of the analyses must be reported along with the residue data. The tests must be conducted in ND where this use in registered.

30/Data requirements regarding the magnitude of residues in animal products will not be determined until all requested data regarding metabolism in animals and magnitude of residues in feed items have been received. On receipt of the data on HCB levels in feed items, the requirements for data on HCB in animal commodities will be determined.

Table A
Generic Data Requirements for Picloram

Data Requirement	Test Substance1/	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission2/
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	TGAI-Acid	A,B,G	Yes	40479413	No	
	K Salt		Yes	40479401	No	
	IOE		Yes	40479407	No	
	TIPA		No		Yes	9 Months
	TEA		No		Yes	9 Months
	IPA		No		Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	TGAI-Acid	A,B,G	Yes	40479414	No	
	K Salt		Yes	40479402	No	
	IOE		Yes	40479408	No	
	TIPA		No		Yes	9 Months
	TEA		No		Yes	9 Months
	IPA		No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	TGAI-Acid	A,B,G	Yes	40479415	No	
	K Salt		Yes	40479403	No	
	IOE		Yes	40479409	No	
	TIPA		No		Yes	9 Months
	TEA		No		Yes	9 Months
	IPA		No		Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	TGAI-Acid	A,B,G	Yes	40479416	No	
	K Salt		Yes	40479404	No	
	IOE		Yes	40479410	No	
	TIPA		No		Yes	9 Months
	TEA		No		Yes	9 Months
	IPA		No		Yes	9 Months

Table A
Generic Data Requirements for Picloram

Data Requirement	Test Substance[1/]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[2/]
§158.135 Toxicology						
ACUTE TESTING (Con't)						
81-5 - Primary Dermal Irritation - Rabbit	TGAI-Acid	A,B,G	Yes	40479417	No	
	K Salt		Yes	40479405	No	
	IOE		Yes	40479411	No	
	TIPA		No		Yes	9 Months
	TEA		No		Yes	9 Months
	IPA		No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	TGAI-Acid	A,B,G	Yes	40479418	No	
	K Salt		Yes	40479406	No	
	IOE		Yes	40479412	No	
	TIPA		No		Yes	9 Months
	TEA		No		Yes	9 Months
	IPA		No		Yes	9 Months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI-Acid	A,B,G	No		No[3/]	
	K Salt		No		No[3/]	
	IOE		No		No[3/]	
	TIPA		No		No[3/]	
	TEA		No		No[3/]	
	IPA		No		No[3/]	

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[2]
§158.135 Toxicology						
SUBCHRONIC TESTING						
82-1 - 90-Day Feeding	TGAI	A,B,G				
- Rodent	Acid,K Salt		Yes	00110537	No	
	IOE		No		Yes	15 Months
	TEA		No		Yes	15 Months
	IPA		No		Yes	15 Months
	TIPA		No		Yes	15 Months
- Nonrodent (Dog)	Acid,K Salt		Yes	00110534	No	
	IOE		No		Yes	18 Months
	TEA		No		Yes	18 Months
	IPA		No		Yes	18 Months
	TIPA		No		Yes	18 Months
82-2 - 21-Day Dermal - Rabbit	TGAI	A,B,G				
	Acid,K Salt		No		Yes	12 Months
	IOE		No		Yes	12 Months
	TEA		No		Yes	12 Months
	IPA		No		Yes	12 Months
	TIPA		No		Yes	12 Months
82-3 - 90-Day Dermal - Rabbit	TGAI	A,B,G				
	Acid,K Salt		No		No[4]	
	IOE		No		No[4]	
	TEA		No		No[4]	
	IPA		No		No[4]	
	TIPA		No		No[4]	

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance1/	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission2/
§158.135 Toxicology						
SUBCHRONIC TESTING (Cont'd)						
82-4 - 90-Day Inhalation	TGAI	A,B,G				
- Rat	Acid,K Salt		No		No4/	
	IOE		No		No4/	
	TEA		No		No4/	
	IPA		No		No4/	
	TIPA		No		No4/	
82-5 - 90-Day Neurotoxicity	TGAI	A,B,G				
- Hen	Acid,K Salt		No		No5/	
	IOE		No		No5/	
- Mammal	TEA		No		No5/	
	IPA		No		No5/	
	TIPA		No		No5/	
CHRONIC TESTING						
83-1 - Chronic Toxicity	TGAI	A,B,G				
- 2 Species	Acid,K Salt		Yes	00155940	No	
- Rodent	IOE		No		Reserved6/	
	TEA		No		Reserved6/	
	IPA		No		Reserved6/	
	TIPA		No		Reserved6/	
- Nonrodent (Dog)	Acid,K Salt		No		Yes7/	
	IOE		No		Reserved6/	
	TEA		No		Reserved6/	
	IPA		No		Reserved6/	
	TIPA		No		Reserved6/	

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[2]
§158.135 Toxicology						
CHRONIC TESTING (Cont'd)						
83-2 - Oncogenicity Study	TGAI					
- 2 Species						
- Rat (preferred)	Acid,K Salt		No		Yes[8]	50 Months
	IOE		No		Reserved[6]	
	TEA		No		Reserved[6]	
	IPA		No		Reserved[6]	
	TIPA		No		Reserved[6]	
- Mouse (preferred)	Acid,K Salt		No		Yes[8]	50 Months
	IOE		No		Reserved[6]	
	TEA		No		Reserved[6]	
	IPA		No		Reserved[6]	
	TIPA		No		Reserved[6]	
83-3 - Teratogenicity	TGAI					
- 2 Species						
- Rat	Acid,K Salt		No		Yes[9]	15 Months
	IOE		No		Yes	15 Months
	TEA		No		Yes	15 Months
	IPA		No		Yes	15 Months
	TIPA		No		Yes	15 Months
- Rabbit	Acid,K Salt		No		Yes	15 Months
	IOE		No		Yes	15 Months
	TEA		No		Yes	15 Months
	IPA		No		Yes	15 Months
	TIPA		No		Yes	15 Months

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[2]
§158.135 Toxicology						
CHRONIC TESTING (Cont'd)						
83-4 - Reproduction - Rat 2-Generation	TGAI	A,B,G				
	Acid,K Salt		No		Yes	39 Months
	IOE		No		Reserved[6]	
	TEA		No		Reserved[6]	
	IPA		No		Reserved[6]	
	TIPA		No		Reserved[6]	
MUTAGENIC TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A,B,G				
	Acid,K Salt		No		Yes[10]	9 Months
	IOE		No		Yes	9 Months
	TEA		No		Yes	9 Months
	IPA		No		Yes	9 Months
	TIPA		No		Yes	9 Months
84-2 - Structural Chromosomal Aberration	TGAI	A,B,G				
	Acid,K Salt		Yes	00098322	No	
	IOE		No		Yes	12 Months
	TEA		No		Yes	12 Months
	IPA		No		Yes	12 Months
	TIPA		No		Yes	12 Months

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance1/	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission2/
§158.135 Toxicology						
MUTAGENIC TESTING (Cont'd)						
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B,G				
	Acid,K Salt		No		Yes	12 Months
	IOE		No		Yes	12 Months
	TEA		No		Yes	12 Months
	IPA		No		Yes	12 Months
	TIPA		No		Yes	12 Months
SPECIAL TESTING						
85-1 - General Metabolism	PAI or TGAI	A,B,G				
	Acid,K Salt		Partially	00098321	Yes11/	24 Months
	IOE		No		Yes	24 Months
	TEA		No		Yes	24 Months
	IPA		No		Yes	24 Months
	TIPA		No		Yes	24 Months

1/Test Substance: Technical grade = acid; Potassium salt of picloram = K Salt; Isooctyl ester = IOE; Triethylamine salt of picloram = TEA; Isopropanolamine salt of picloram = IPA; and Triisopropanolamine salt of picloram = TIPA.

2/Data must be submitted within the indicated timeframe, based on date of this Guidance Document.

3/This test is required only for compounds which are organophosate inhibitors of cholinesterase, or related to such inhibitors or metabolites of such inhibitors. Picloram, its esters, salts, or amines are not organophosates; therefore, these data are not required.

4/This study is not required based on existing use patterns.

5/This study is not required since an acute neurotoxicity study is not required for this compound and there is no evidence of neurotoxicity in mammalian species.

Table A
Generic Data Requirements for Picloram (Cont'd)

Footnotes (Cont'd)

6/Requirement reserved. Required if measurable residues of the particular amine or ester group are present on the RACs or processed foods or if basic toxicology studies required show differences in toxic effect(s) compared with picloram and/or its organic salts.

7/This study (MRID No. 40834301) was submitted too late to be included in this standard.

8/Rodent studies should be in the Osborne-Mendel rat and the B6C3F1 mouse using commercially available technical grade picloram uncontaminated with potentially tumorigenic levels of HCB. The registrant should consult with the Agency in order to establish appropriate doses for these studies.

9/A new study with rabbits is needed or additional information clarifying abnormalities noted in the previously submitted study (MRID No. 00138703).

10/Data and raw report materials supporting the qualitative statements made on the previous study (MRID No. 00138793) must be submitted or a new study must be submitted.

11/This study is acceptable for males. Only females must be tested in the additional study.

Table A
Generic Data Requirements for Picloram

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[1/]
§158.290 Environmental Fate						
DEGRADATION STUDIES - LAB						
161-1 - Hydrolysis	PAIRA	A,B,D,G	Yes	00131365 00164749	No	
Photodegradation						
161-2 - In Water	PAIRA	A,B,D,G	No		Yes	9 Months[2/]
161-3 - On Soil	PAIRA	A,G	No		Yes	9 Months[2/]
161-4 - In Air	PAIRA	A	No		No[3/]	
METABOLISM STUDIES - LAB						
162-1 - Aerobic Soil	PAIRA	A,B,G	Yes	00128976 40178601	No	
162-2 - Anaerobic Soil	PAIRA	A	Yes	00128976	No	
162-3 - Anaerobic Aquatic	PAIRA	D,G	Partially	00128976	Yes[4/]	27 Months
162-4 - Aerobic Aquatic	PAIRA	D	No		Yes[2/]	27 Months
MOBILITY STUDIES						
163-1 - Leaching and Adsorption/Desorption	PAIRA	A,B,D,G	No		Yes[5/]	12 Months
163-2 - Volatility (Lab)	TEP	A	No		No[3/]	
163-3 - Volatility (Field)	TEP	A	No		No[3/]	

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[1]
§158.290 Environmental Fate						
DISSIPATION STUDIES - FIELD						
164-1 - Soil	TEP	A,B	No		Yes[6]	27 Months
164-2 - Aquatic (Sediment)	TEP	D	No		Yes[7]	27 Months
164-3 - Forestry	TEP	G	No		Yes[8]	27 Months
164-4 - Combination and Tank Mixes			N/A		No[9]	--
164-5 - Soil, Long-Term	TEP	A	No		Reserved[10]	
ACCUMULATION STUDIES						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes[11]	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No		Reserved[12]	
165-3 - Irrigated Crops	TEP	D	No		Yes[13]	39 Months
165-4 - In Fish	PAIRA	A,B,D,G	Partially	00128947	Yes[14]	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP	D,G	No		Reserved[15]	
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B,D,G	No		No[16]	
132-2 - Soil Dissipation	TEP	A,B,D,G	No		No[16]	

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[1/]
§158.140 Reentry Protection (Cont'd)						
133-3 - Dermal Exposure	TEP	A,B,D,G	No		No[16/]	
133-4 - Inhalation Exposure	TEP	A,B,D,G	No		No[16/]	
§158.142 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A,B,D,G	No		Yes[17/]	18 Months
201-1 - Drift Field Evaluation	TEP	A,B,D,G	No		Yes[17/]	18 Months
§158.75 Other Exposure Data						
Mixer/Loader and Applicator Exposure Data			No		No	
Groundwater Monitoring Data			No		Yes[18/]	10 Months

1/Data must be submitted within the indicated timeframe, based on the date of the Guidance Package.

2/Data are needed for both the isooctyl ester (IOE) and potassium (K) salt forms of picloram. For the aerobic aquatic studies, the use on outer ditch banks is an aquatic use and must be supported by the required data or withdrawn.

3/No data are required because of the relatively low vapor pressure of picloram salt form. No data are required for the IOE form because there are no terrestrial food uses presently registered for this form.

4/Additional data are needed for the IOE form of picloram, to support the aquatic use on ditchbanks or this use must be withdrawn.

5/Data needed on both the K salt and IOE forms. An adsorption/desorption (batch equilibrium) type of mobility study must be conducted on four soil types at four concentrations.

Table A
Generic Data Requirements for Picloram (Cont'd)

Footnotes (Cont'd)

6/Nine soil dissipation studies are needed covering the following test parameters:

	Chemical Form.	Use Pattern	Location
1.	Triisopropanolamine salt	Rights-of-way	Anywhere in U.S. (2 sites)
2.	Isooctyl ester	Rights-of-way	Anywhere in U.S. (2 sites)
3.	Potassium salt	Small grain	ID, OR, or WA
4.	Potassium salt	Nonfood	Anywhere in U.S. (2 sites)
5.	Potassium salt	Pasture/Rangeland	Anywhere in U.S. (2 sites)

These studies must be conducted at the maximum application rate as specified by the product labels. The nine studies required for the Terrestrial Field Dissipation requirement include all three registered formulations of picloram and the most typical use patterns. The potassium salt formulation should not be mixed with another pesticide, whereas the triisopropanolamine salt formulation must include 2,4-D and the isooctyl ester formulation must include triclopyr, as these formulations typically contain these compounds.

7/Additional data are needed to support the use of the soluble concentrate/liquid formulation (TIPA) in ditchbanks.

8/Data are needed to support forest site preparation by broadcast application of the K salt form in two representative areas of the United States, the South and Northwest.

9/Data for this requirement are no longer necessary.

10/Data may be required on the K and IOE forms of picloram if the results from the field dissipation studies demonstrate that residues do not reach 50 percent dissipation in soil prior to the recommended subsequent application.

11/Data are needed for the K form of picloram only. The IOE form is not presently registered for use on terrestrial food crops.

12/Pending the results of an acceptable confined rotational crop study.

13/Data are required for both the K and IOE forms of picloram, to support the aquatic use on ditchbanks or the use must be withdrawn.

14/Additional data are needed for the IOE form of picloram.

15/Reserved pending the results of an acceptable fish accumulation study with the IOE form of picloram.

16/Picloram does not meet the toxicology requirements of Part 158.140 of Title 40 of the Code of Federal Regulations.

17/The Spray Drift Droplet Spectrum and Field Evaluation may be done together in order to evaluate the droplet spectra that are associated with actual field use patterns. The droplet spectrum study is to be performed to reflect the nozzle and other equipment types to be used in the application of picloram to pasture/rangeland, rights-of-way, and forestry uses. The Spray Drift Field Evaluation is to be performed to reflect the application of equipment, use pattern, and typical locations of use, which include different weather factors, in the application of picloram for these uses.

Table A
Generic Data Requirements for Picloram (Cont'd)

Footnotes (Cont'd)

18/The prospective study is due to be submitted by July 1989. The Agency reserves the right to request further groundwater monitoring studies, if (1) after rview of the protocol for the prospective study it is determined that the study is not adequately designed to answer the Agency's questions regarding the groundwater contamination hazard by picloram; or (2) after submission of the prospective study it is determined that a more widespread characterization of the groundwater contamination hazard with picloram is needed.

Table A
Generic Data Requirements for Picloram

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission1/
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral	TGAI	A,B,G				
	Acid		Yes	00157173	No2/	
	K Salt		Yes	00157174	No2/	
71-2 - Avian Subacute Dietary Toxicity	TGAI	A,B,G				
- Upland Game Bird	Acid		Yes	00022923	No2/	
	K Salt		Yes	00164727		
	IOE		Yes	00164726		
- Waterfowl	Acid		Yes	00022923	No2/	
71-3 - Wild Mammal Toxicity	TGAI	A,B,G	No		No3/	
71-4 - Avian Reproduction	TGAI	A,B,G				
- Upland Game Bird			No		No4/	
- Waterfowl			No		No4/	
71-5 - Simulated Field Testing	TEP	A,B,G				
- Mammals			No		No5/	
- Birds			No		No5/	
71-5 - Actual Field Testing	TEP	A,B,G				
- Mammals			No		No5/	
- Birds			No		No5/	

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission1/
§158.145 Wildlife and Aquatic Organisms						
AQUATIC ORGANISMS TESTING						
72-1 - Freshwater Fish LC_{50}	TGAI	A,B,G				
- Warmwater	Acid		Yes	00129076	No2/	
	K Salt		Yes	00041475		
	IOE		Yes	40094602		
- Coldwater	Acid		Yes	00129076 00129078	No2/	
	K Salt		Yes	00041475		
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI (Acid)	A,B,G	Yes	00129076 00141979 00151783 40094602	No2/	
72-3 - Acute Toxicity to Estuarine and Marine Organisms - Fish - Mollusk - Shrimp	TGAI	A,B,G	Yes	00111560 00129073	No2/	
72-4 - Fish and Early Life Stage and Aquatic Invertebrate Life Cycle	TGAI	A,B,G	Yes	00129085 00151784	No2/	
72-5 - Fish Life Cycle	TGAI	A,B,G	No		No	

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[1]
§158.145 Wildlife and Aquatic Organisms						
AQUATIC ORGANISMS TESTING (Cont'd)						
72-6 - Aquatic Organism Accumulation - Crustacean	TGAI, PAI or Degradation Product	A,B,G	Yes	00128947	No	
- Fish						
- Insect Nymph						
- Mollusk						
72-7 - Simulated Field Testing - Aquatic Organisms	TEP		No		No[6]	
72-7 - Actual Field Testing - Aquatic Organisms			No		No[6]	

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[1] Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.

[2] Additional testing will not be required on picloram derivatives (potassium salt, isooctyl ester), because of the similarity in toxicity values that were noted in available data.

[3] These data are required if available acute toxicology data indicate an acute hazard. Available data do not trigger this requirement.

[4] These data are required only when the label recommends multiple applications. Picloram labels do not recommend multiple applications.

[5] These data are required if available acute data on birds and mammals indicate an acute hazard. The available data do not trigger these requirements.

[6] These studies are required if available acute toxicology data on aquatic organisms indicate an acute hazard. Available data do not trigger these requirements.

Table A
Generic Data Requirements for Picloram (Cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[1/]
§158.150 Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	EP	B	No		No[2/]	
NONTARGET AREA PHYTOTOXICITY						
TIER I						
121-1 - Seed Germination/ Seedling Emergence	TGAI	B	No		No[3/]	
122-1 - Vegetative Vigor	TGAI	B	No		No[3/]	
122-2 - Aquatic Plant Growth	TGAI	B	No		No[3/]	
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI-Acid	B	No		Yes[4/]	9 Months
	K Salt	B	No		Yes[4/]	9 Months
	IOE		No		Yes[4/]	9 Months
123-1 - Vegetative Vigor	TGAI-Acid	B	No		Yes[4/]	9 Months
	K Salt	B	No		Yes[4/]	9 Months
	IOE		No		Yes[4/]	9 Months
123-2 - Aquatic Plant Growth	TGAI-Acid	B	No		Yes[4/]	9 Months
	K Salt	B	No		Yes[4/]	9 Months
	IOE		No		Yes[4/]	9 Months
TIER III						
124-1 - Terrestrial Field	TEP	B	No		Reserved[5/]	
124-2 - Aquatic Field	TEP	B	No		Reserved[5/]	

Table A
Generic Data Requirements for Picloram (Cont'd)

§158.150 Plant Protection Footnotes

1/Data must be submitted within the indicated timeframe based on the date of the Guidance Document.
2/Not required because picloram is not in Special Review and there are no current health considerations.
3/Not required because the Agency is requiring Tier II testing.
4/The testing will be required on the technical active ingredient for each derivative (acid, potassium (K) salt, and isooctyl ester), because picloram is a herbicide and phytotoxicity testing is required to determine hazard to nontarget plants.
5/This requirement is reserved pending results of Tier II testing.

Table A
Generic Data Requirements for Picloram

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission1/
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS						
141-1 - Honey Bee Acute Contact Toxicity	TGAI-Acid	A,B,G	Yes	00036935	No	
	K Salt		No		Yes2/	9 Months
	TEA Salt		No		Yes2/	9 Months
	IOE Salt		No		Yes2/	9 Months
	TIPA Salt		No		Yes2/	9 Months
	IPA Salt		No		Yes2/	9 Months
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	A,B,G	No		Reserved3/	
141-4 - Honey Bee Subacute Feeding Study	(Reserved)4/					
141-5 - Field Testing for Pollinators	TEP	A,B,G	No		Reserved5/	
NONTARGET INSECT TESTING - AQUATIC INSECTS						
142-1 - Acute Toxicity to Aquatic Insects	(Reserved)6/					
142-2 - Aquatic Insect Life Cycle Study	(Reserved)6/					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	(Reserved)6/					
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved)6/					

Table A
Generic Data Requirements for Picloram (Cont'd)

§158.590 Nontarget Insect Footnotes

1/Data must be submitted within the indicated timeframe, based on date of this Guidance Document.

2/The data are required for outdoor uses which may result in exposure of honey bees to the pesticide. Testing is required on picloram derivatives (potassium (K) salt, triethylamine (TEA) salt, isooctyl ester (IOE), triisopropanolamine (TIPA) salt, and isopropylamine salt (IPA)).

3/Requirement for these data will depend upon the result of acute studies.

4/This requirement reserved pending development of test methodology.

5/This requirement will depend upon results of lower-tier testing.

6/These requirements reserved pending Agency decision as to whether the data requirement should be established.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products and Formulation Intermediates Containing Picloram

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[2]
§158.120 Product Chemistry						
Product Identity and Composition						
61-1 - Product Identity and Disclosure of Ingredients	MP	All				
	K Salt		No		Yes[3]	6 Months
	TIPA		No		Yes[4]	6 Months
	IOE		No		Yes[4]	6 Months
	TEA		No		Yes[4]	6 Months
	IPA		No		Yes[4]	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All				
	K Salt		No		Yes[5]	6 Months
	TIPA		No		Yes[5]	6 Months
	IOE		No		Yes[5]	6 Months
	TEA		No		Yes[5]	6 Months
	IPA		No		Yes[5]	6 Months
61-3 - Discussion of Formation of Impurities	MP	All				
	K Salt		Yes	00154235	No	
	TIPA		No		Yes[6]	
	IOE		No		Yes[6]	
	TEA		No		Yes[6]	
	IPA		No		Yes[6]	

Table B
Product-Specific Data Requirements for Manufacturing-Use Products and Formulation Intermediates Containing Picloram (Cont'd)

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[2]
§158.120 Product Chemistry						
Analysis and Certification of Product Ingredients (Cont'd)						
62-1 - Preliminary Analysis	MP	All				
	K Salt		Yes	00154235	No	
	TIPA		No		Yes[7]	12 Months
	IOE		No		Yes[7]	12 Months
	TEA		No		Yes[7]	12 Months
	IPA		No		Yes[7]	12 Months
62-2 - Certification of Limits	MP	All				
	K Salt		Partially	00154235	Yes[8]	12 Months
	TIPA		No		Yes[8,9]	12 Months
	IOE		No		Yes[8]	12 Months
	TEA		No		Yes[8,9]	12 Months
	IPA		No		Yes[8]	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	All				
	K Salt		Yes	00154235 40588501	No	
	TIPA		No		Yes[10]	12 Months
	IOE		Yes	00154235 40588501	No	
	TEA		No		Yes[10]	12 Months
	IPA		Yes	00154235 40588501	No	
63-2 - Color	MP	All				
	K Salt		Yes	40588501	No	
	TIPA		No		Yes	6 Months
	IOE		No		Yes	6 Months
	TEA		No		Yes	6 Months
	IPA		No		Yes	6 Months

Table B
Product-Specific Data Requirements for Manufacturing-Use Products and Formulation Intermediates Containing Picloram (Cont'd)

Data Requirement	Test Substance[1/]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[2/]
§158.120 Product Chemistry						
Analysis and Certification of Product Ingredients (Cont'd)						
63-3 - Physical State	MP	All				
	K Salt		Yes	40588501	No	
	TIPA		No		Yes	6 Months
	IOE		No		Yes	6 Months
	TEA		No		Yes	6 Months
	IPA		No		Yes	6 Months
63-4 - Odor	MP	All				
	K Salt		Yes	40588501	No	
	TIPA		No		Yes	6 Months
	IOE		No		Yes	6 Months
	TEA		No		Yes	6 Months
	IPA		No		Yes	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	MP	All				
	K Salt		Yes	40588501	No	
	TIPA		No		Yes	6 Months
	IOE		No		Yes	6 Months
	TEA		No		Yes	6 Months
	IPA		No		Yes	6 Months
63-12 - pH	MP	All				
	K Salt		Yes	40588501	No	
	TIPA		No		Yes	6 Months
	IOE		No		Yes	6 Months
	TEA		No		Yes	6 Months
	IPA		No		Yes	6 Months

Table B
Product-Specific Data Requirements for Manufacturing-Use Products and Formulation Intermediates Containing Picloram (Cont'd)

Data Requirement	Test Substance[1/]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[2/]
§158.120 Product Chemistry						
Analysis and Certification of Product Ingredients (Cont'd)						
63-14 - Oxidizing or Reducing Action	MP	All				
	K Salt		Yes	40588501	No	
	TIPA		No		Yes	6 Months
	IOE		No		Yes	6 Months
	TEA		No		Yes	6 Months
	IPA		No		Yes	6 Months
63-15 - Flammability	MP	All				
	K Salt		Yes	40588501	No	
	TIPA		No		Yes	6 Months
	IOE		No		Yes	6 Months
	TEA		No		Yes	6 Months
	IPA		No		Yes	6 Months
63-16 - Explodability	MP	All				
	K Salt		Yes	40588501	No	
	TIPA		No		Yes	6 Months
	IOE		No		Yes	6 Months
	TEA		No		Yes	6 Months
	IPA		No		Yes	6 Months
63-17 - Storage Stability	MP	All				
	K Salt		Yes	40588501	No	
	TIPA		No		Yes	15 Months
	IOE		No		Yes	15 Months
	TEA		No		Yes	15 Months
	IPA		No		Yes	15 Months

Table B

Product-Specific Data Requirements for Manufacturing-Use Products and Formulation Intermediates Containing Picloram (Cont'd)

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[2]
§158.120 Product Chemistry						
Analysis and Certification of Product Ingredients (Cont'd)						
63-18 - Viscosity	MP	All				
	K Salt		Yes	40588501	No	
	TIPA		No		Yes[12]	6 Months
	IOE		No		Yes[12]	6 Months
	TEA		No		Yes[12]	6 Months
	IPA		No		Yes[12]	6 Months
63-19 - Miscibility	MP	All				
	K Salt		Yes	40588501	No	
	TIPA		No		Yes[13]	6 Months
	IOE		No		Yes[13]	6 Months
	TEA		No		Yes[13]	6 Months
	IPA		No		Yes[13]	6 Months

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[1] Test Substance: Potassium salt of picloram = K Salt; Triisopropanolamine salt of picloram = TIPA; Isooctyl ester = IOE; Triethylamine salt of picloram = TEA; and Isopropanolamine salt of picloram = IPA.

[2] Data must be submitted within the indicated timeframe, based on date of this Guidance Document.

[3] Nominal concentrations for active ingredient and each intentionally added inert must be submitted. The name and upper certified limit must be provided for each impurity or group of impurities for which a certified limit is required. This information must be submitted on EPA Form 8570-4.

[4] The product name, chemical name, nominal concentration, certified limits, CAS Registry Number, and purpose of each intentionally-added inert must be provided for the TIPA, IOE, TEA, AND IPA end-use products (EPs). The name and upper certified limit must be provided for each impurity or group of impurities for which a certified limit is required for all EPs produced by an integrated formulation system. This information must be submitted on EPA Form 8570-4.

[5] Complete information must be submitted for the K salt and all EPs produced by an integrated formulation system regarding the nature of the process (batch or continuous); the relative amounts of beginning materials, the

Table B
Product-Specific Data Requirements for Manufacturing-Use Products and Formulation Intermediates Containing Picloram (Cont'd)

Footnotes (Cont'd)

chemical equation for each reaction, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, supplier, or producer of each beginning material used in the manufacture of the EPs produced by an integrated formulation system, and information regarding the properties of each beginning material used in the manufacture of the K salt and EPs produced by an integrated formulation system must be provided.

6/A detailed discussion of all impurities that are or may be present at $\geq$ 0.1% in all EPs produced by an integrated formulation system, based on knowledge of beginning materials, chemical reactions (intended and side) in the manufacturing process and any contamination during and after production must be submitted.

7/Five or more representative samples of each of the EPs produced by an integrated formulation system must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

8/Upper and lower limits for the active ingredient and each intentionally added inert and upper limits for each impurity present at $\geq$ 0.1% (w/w) and each additional "toxicologically significant" impurity present at < 0.1% (w/w) are required for the K salt and all EPs produced by an integrated formulation system. Limits must be certified and an explanation of how each certified limit was established must be provided. Certification will be specifically required for the toxicologically significant impurity hexachlorobenzene (HCB). Certification must be submitted on EPA Form 8570-4.

9/Validated certified limits for N-nitroso contaminants are required for all EPs that contain tertiary alkanolamines or tertiary amines. The nitrosamines must be identified in six samples of each product; two samples must be analyzed shortly after production, 3 months after production, and 6 months after production. A method of sensitivity to 1 ppm of N-nitroso contaminants must be used.

10/Analytical methods must be provided to determine N-nitrosoamines in all EPs containing tertiary alkanolamines or tertiary amines. The method must be accompanied by validation studies indicating the accuracy and precision.

11/Data are required on pH if the test substance can be diluted or dispersed in water.

12/Data on viscosity are needed if the product is a liquid.

13/Data on miscibility are required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products and Formulation Intermediates Containing Picloram

Data Requirement	Test Substance$^{1/}$	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission$^{2/}$
§158.340 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	MP	A,B,G				
	K Salt		Yes	40479401	No	
	IOE		Yes	40479407	No	
	TEA		No		Yes	9 Months
	IPA		No		Yes	9 Months
	TIPA		No		Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	A,B,G				
	K Salt		Yes	40479402	No	
	IOE		Yes	40479408	No	
	TEA		No		Yes	9 Months
	IPA		No		Yes	9 Months
	TIPA		No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	A,B,G				
	K Salt		Yes	40479403	No	
	IOE		Yes	40479409	No	
	TEA		No		Yes	9 Months
	IPA		No		Yes	9 Months
	TIPA		No		Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	A,B,G				
	K Salt		Yes	40479404	No	
	IOE		Yes	40479410	No	
	TEA		No		Yes	9 Months
	IPA		No		Yes	9 Months
	TIPA		No		Yes	9 Months

Table B
Product-Specific Data Requirements for Manufacturing-Use Products and Formulation Intermediates Containing Picloram (Cont'd)

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission[2]
§158.340 Toxicology						
ACUTE TESTING (Cont'd)						
81-5 - Primary Dermal Irritation - Rabbit	MP	A,B,G				
	K Salt		Yes	40479405	No	
	IOE		Yes	40479411	No	
	TEA		No		Yes	9 Months
	IPA		No		Yes	9 Months
	TIPA		No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	A,B,G				
	K Salt		Yes	40479406	No	
	IOE		Yes	40479412	No	
	TEA		No		Yes	9 Months
	IPA		No		Yes	9 Months
	TIPA		No		Yes	9 Months

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[1] Test Substance: Potassium salt of picloram = K Salt; Isooctyl ester of picloram = IOE; Triethylamine salt of picloram = TEA; Isopropylamine salt of picloram = IPA; and Triisopropanolamine salt of picloram = TIPA.

[2] Data must be submitted within the indicated timeframe, based on date of this Guidance Document.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 156.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.56(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of Part 152, Subpart I. You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv)

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

   b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

   c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§156.10 Labeling Requirements for Pesticides and Devices.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";
(B) "Among the least toxic chemicals known"
(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) *Directions for Use*--(1) *General requirements*--(i) *Adequacy and clarity of directions*. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use*. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978; amended at 53 FR 15952, May 4, 1988]

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

BIBGUIDE-1

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

  (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

  (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

  (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

  (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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IV. FORM APPENDICES

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number:____________________
Registrant's Name and Address: ____
____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated ________ concerning a requirement for submission of "generic" data on the active ingredient _______________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated ___________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are _________ and their registration number(s) is/are _________.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative:________________________________
(Signature)

Dated: ____________________ ________________________________
(Typed)

EPA Form 8570-3

OMB Approval No. 2070-0057
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date____________________

Guidance Document for____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

OMB Approval No. 2070-0057
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PRODUCT SPECIFIC DATA REPORT (cont'd)

EPA Reg. No.________________________ Date__________________________

Guidance Document for____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
Subpart C PRODUCT CHEMISTRY (cont'd)					
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.340 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization.				
81-7	Acute Delayed neurotoxicity, hen				

EPA Form 8580-4 (cont'd)

EPA Form 8580-6

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT
NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE